

Terms of Reference Version 3.0 (23 February 2024)

Introduction

The Science Council will convene and coordinate a Pilot Expert Working Group (WG) addressing the consideration of wider impacts beyond risk assessment. The WG is asked to report on how “wider impacts” may be evidenced in support of risk management decisions.

The Codex principles on risk analysis ([CXG 62-2007](#)) require a functional separation of risk assessment and risk management. This was incorporated into the Science Council's principles on [risk and uncertainty](#), and subsequently agreed by FSA Board in [September 2018](#). This was embedded in the FSA/FSS risk analysis process which, for example, includes the following: “In line with Codex principles, risk assessments are produced separately from reports on Other Legitimate Factors (OLFs) to ensure the scientific integrity of the risk assessment and protect the independence of the process. It is important that OLFs do not influence the risk assessment. It is not within a risk assessor’s remit to consider OLFs, which are instead assessed and documented separately by others with appropriate expertise such as social scientists and economists.”

The competence of the Science Council lies within the scientific domain, and it is proposed to limit discussions to the provision of scientific advice on wider impacts supplementary to the process of providing advice on defined food safety questions. With this boundary, there will be a need to acquire appropriate input from disciplines not currently represented on the Science Council (e.g., Nutrition, Environmental Science, Risk Psychology).

The term “wider impacts” is broader than “OLFs” or risk-benefit. The terminology “risks” and “benefits” although important for communication, may create an illusion of simplicity. Equally, so-called benefits may not be easily compared or quantified. The spirit of current regulations or government policy may frame the advice, and the background context will be valuable in helping decision makers. In meeting the objectives of the project, the WG will consider deliberate and

unintended consequences. There may be a shortage of data with which to consider wider impacts. In such circumstances technical experts may provide advice on opportunities to improve understanding of risks and other factors.

Structure: potential phases of work

The Expert Group will consider wider impacts as an ad hoc or “mock” SAC tasked with identifying the layers of evidence that would be required if these wider impacts were to be included in the evidence package.

Phase 1 (December 2023-January 2024)

It will use as a starting point current principles in use by FSA and review practices employed elsewhere. The preliminary review will draw on concrete examples from previous regulatory and policy decisions. Risk governance expertise will be used to provide guidance on appropriate structure and application of correct and consistent terminology. It will identify the broad areas of expertise that might be needed in order to assess the evidence requirements associated with wider impacts for the three case studies agreed.

Phase 2 (January-March 2024)

It is proposed to support the development of principles with the aid of three case studies where the context is:

1. When both chemical and microbial risks need to be considered together.
2. When food safety advice is formulated where environmental benefits and risks are at play.
3. Where food safety advice is formulated where nutritional factors need to be considered.

The cases will be formulated based on a satisfactory assessment of available evidence. It is proposed to assess sodium nitrite, seaweed and aspartame, respectively, for the above cases. A short white paper will be prepared for each topic to be discussed at a “mock” SAC meeting. The case studies will be led by Science Council members drawing in appropriate expertise on each topic. Science Council members will act as rapporteurs for each of the cases. The purpose of the “mock SAC” is not to provide or assess the evidence relating to wider impacts for each of these three cases (which would be a lengthy and complex undertaking),

but rather to identify.

A. What types of evidence would be required for such an assessment.

B. Whether such evidence is likely to be available 'up front' or would require *de novo* research.

C. The nature of the expertise that FSA would require to assess these wider impacts.

Phase 3 (March-May 2024)

The process employed during the analysis of the case studies will be evaluated. The approach used in Phase 1 and Phase 2 will allow for the elaboration of both general principles and specific considerations informed by the analysis of case studies. The outcomes of the "mock" SAC discussions will be organised into a report for further input from the invited experts.

1. The WG will propose a set of working principles supported by a decision tree that may be used in the context of incorporating wider impacts in Risk Management and Food Policy considerations.
2. Three selected case studies will be provided working through agreed principles and available evidence with which to consider wider impacts in the context of a) Food safety risk comparisons; b) Food safety and environmental risk/benefit considerations; and c) Food safety and nutritional risk/benefit considerations.
3. The Science Council will provide a set of suggestions for evaluation of wider impacts evidence addressing general principles and considerations and within the context of the specific case topics explored in (2) above.
4. The Science Council will produce a report, detailing how the process ran, what potential pitfalls were identified, where additional data would have been required, etc. The report will give a qualitative assessment of the likely time and resource requirements of such an approach.
5. A maximum of three 'draft' versions of the report will be produced. The first draft will be produced after the 'mock' SAC; the second draft will incorporate additional expert input and the third draft will be produced for sign off by Science Council and the FSA.
6. The output of this WG will primarily be based on scientific evidence and considerations; therefore, the primary FSA customer will be SERD. However, the

impact and recommendations will be of relevance to multiple internal stakeholders.

Governance

The WG will be chaired by John O'Brien of the Science Council, with Peter Gregory acting as deputy Chair.

Secretariat role

Secretariat will provide organisational support to the WG. This will include a co-ordination role (e.g. contacting experts) and administrative support (e.g. arranging scheduled project meetings). This will not include the production of technical or analytical material, which will be provided by the relevant experts.

Production of project management documents, such as Terms of Reference, project delivery schedule, meeting papers and project report will be produced by the WG in consultation with FSA.

FSA participants

Robin May (Chief Scientific Adviser)

Michelle Patel (Deputy Director of SERD)

Peter Quigley (Deputy Director of Regulatory Services)

Thomas Vincent (Head of Food Policy)

Joanne Edge (Team Leader – Science Governance)

Eirini Petratou (Economic Adviser)

FSA Inputs

Procurement and finance input to commissioning of the any preparatory work needed to provide support materials for one planned workshop.

The Science Council will co-opt external members of the WG as needed to assist with the delivery of this project.

Other inputs as required by the WG, but likely to include:

- Draw on leads/contacts in other government departments (e.g. Go-Science, Defra, DHSC/SACN, OPSS, FSS, Department for Business & Trade). General risk governance expertise and experience in a scientific setting would be particularly welcome.
- As an ongoing task - considering what other inputs the WG needs in terms of expertise/insight/commentary as well as of written material.

SAC Inputs

We envisage drawing on expertise within several FSA SACs and non-FSA SACs (e.g., SACN; Defra Science Council) to help address facets of the work programme. In particular, the Advisory Committee on Social Science (ACSS) has expertise on the psychology of risks and benefits; both the Advisory Committee on the Microbial Safety of Foods (ACMSF) and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) provide expert advice on complex food safety matters that form the basis for risk management and policy decisions; the Advisory Committee on Animal Feedingstuffs (ACAF) and the Advisory Committee on Novel Foods and Processes (ACNFP) provide advice on regulated products that may have impacts on the environment.