Science Council Rapid Evidence Review: The Critical Appraisal of Third-Party Evidence

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1. Summary

1.1 Attached in the **Annex** to this paper are the proposed Terms of Reference (ToRs) for a review seeking the Science Council's advice and recommendations on a clear, robust and defensible screening process for assessing the quality of third party science and evidence submitted to the Food Standards Agency (FSA) in an effort to influence its policy.

1.2 The Science Council is asked to:

- **Review** and **Agree** the drafted ToRs for the Council's Rapid Evidence Review.
- **Consider** Council members leadership of the proposed Work Packages.

2. Introduction

2.1 The FSA is increasingly expected to form an independent position in response to a greater volume of evidence submitted by third parties in an effort to change its policy.

2.2 In March 2020 the FSA Chair, Heather Hancock, asked the Science Council for its guidance on quality and assurance thresholds for third party science and evidence (FSA 20-06-01).

2.3 The proposed ToRs have been drafted in consultation FSA's Chief Scientific Adviser, the Science Council Chair and FSA Officials in the Wales, Information and Science Directorate.

Annex

Science Council Rapid Evidence Review:

The Critical Appraisal of Third-Party Evidence

Introduction

The United Kingdom has left the European Union, with the EU transition period ending 31st December 2020. The independent advice and recommendations the Food Standards Agency (FSA) provides will be expected to withstand further external scrutiny following the end of the transition period[1].

Transparency in the use of robust science and evidence is central to the FSA's mission, including its risk analysis process. The FSA seeks to ensure that its advice and recommendations are made on the best-available evidence. In March 2020[2] the FSA Chair, Heather Hancock, asked the Science Council for its guidance on quality and assurance thresholds for third party science and evidence. This recognises that the FSA is increasingly expected to form an independent position in response to a greater volume of evidence submitted by third parties in an effort to change our policy.

The Science Council seeks to provide a set of principles/guidelines, providing assurance that the FSA will deliver a clear, robust and defensible screening process to filter out poor/weak evidence i.e. a minimum standards threshold for the objective, critical appraisal of third-party evidence submitted to the FSA in an effort to change policy. Making these guidelines readily available helps ensure regulation of our food system remains transparent, supporting robust and assured engagement between the FSA and industry, helping to put safety at the heart of food system innovation and change.

> **Question**: How should the FSA evaluate the robustness of evidence submitted by non-commissioned third parties in an effort to change our policy, in order to ensure that the evidence considered to inform our advice and recommendations is

[1] https://www.food.gov.uk/business-guidance/the-uk-transition
[2] https://www.food.gov.uk/sites/default/files/media/document/minutes-march-2020-board-meeting-and-business-committee.pdf

sufficiently robust and based on the most up to date scientific information?

Scope

The Science Council seek to provide assurance to the FSA's independent articulation of what it considers 'quality', or robust, evidence.

Significant guidance on study design and the critical appraisal of evidence is already available from for example: Codex Alimentarius, the European Food Safety Authority (EFSA) and the Organisation for Economic Co-operation and Development (OECD). Such examples of international best practice set a minimum standard for the United Kingdom.

The scope of this work will consider standards for information provided within four broad categories:

- Academic opinion
- Academic evidence
- Industry/stakeholder opinion
- Industry/stakeholder evidence

There are many themes linked to the critical appraisal of third-party evidence that the Science Council may wish to consider. These include, though are not limited to:

- Articulating 'quality' based on relevance, adequacy and reliability;
- Objectively assessing the value of 'grey' evidence sources, including independent 'expert' knowledge elicitation and the growing implications of open peer review, in particular the availability of preprints;
- Handling uncertainty;
- Dealing with complexity i.e. multifactorial issues;
- The durability and consistency of evidence;
- Impartiality, bias and responsibility;
- Ensuring evidence needs and its critical appraisal remain appropriate and proportionate to the relevant risks and interests;
- 'Safeguards': reputation and ethics, accountability and liability;
- Effectively minimising ambiguity on expected evidence standards for third parties.

The scope will not include:

- Evidence that the FSA has directly commissioned, though may be informed by FSA guidance for the evaluation of commissioned evidence, or;
- The assessment of dossiers submitted by companies or countries for the pre-market approval or post-market review of regulated food and feed products.

Annex 2 provides an initial summary of scoping literature relevant for further consideration.

Anticipated Outputs

The Science Council's rapid evidence review on the critical appraisal of third-party evidence is intended to support the FSA following the end of the EU transition period. The Science Council will deliver an evidence threshold 'checklist' supporting the objective, critical appraisal of third-party evidence submitted to the FSA in an effort to change policy, in December 2020. A full report will be made available to the FSA Board shortly after, for open discussion on the 10th March 2021 or as otherwise felt appropriate, providing further strategic advice and assurance on the adaptive capability of FSA processes for the appraisal of third-party evidence.

Approach

The Science Council's rapid evidence review on the critical appraisal of third-party evidence will consist of four interlinked Work Packages:

Work Package 1: Desk Study (September 2020 - November 2020)

- Interviews with relevant FSA and Food Standards Scotland (FSS) leads to understand current practice i.e. policy leads, risk assessment leads, analytics lead supporting evidence needs related to 'other legitimate factors' etc.
- Literature review of existing international guidance for evidence quality and review, from those with an interest in food safety.
- Consider the need to consult a small number of independent informants early in this evidence review.
- Update on FSA actions in response to Science Council Working Group 1 recommendations.
- Review FSA guidance of transferable interest i.e. draft science 'checklist' and sampling strategy.

Work Package 2: FSA Science Advisory Committee (SAC) Consultation (September 2020 - November 2020)

- Written evidence requests on existing SAC processes for the critical appraisal of evidence.
- Engage with SAC Chairs as key peer review group for drafted Science Council principles and guidance.

Work Package 3: Consultation with Other Government Departments (OGDs)

(September 2020 - November 2020)

- Review best practice guidance within OGDs, as requested through the Chief Scientific Adviser (CSA) Network and cross-gov SAC Network. Request to be followed up with interviews/further discussions as appropriate.
- Departments or Agencies for prioritisation include: Go-Science, APHA, PHE, ONS, HSE, VMD, MHRA, BEIS and Defra.

Work Package 4: Stakeholder Consultation (October 2020 - January 2021)

- A wider consultation aimed to capture key concerns and experience from stakeholders that may include for example: trade bodies, NFU, UKAS, Fera, LGC, Campden BRI, IRGC.
- The start of Work Package 4 will be delayed, being informed by Work Packages 1-3. Consultation will last for a six-week period.
- Work Package 4 will complete in January 2021, for discussion as part of the Science Council final report.

Membership

Given the pace of this Evidence Review, it will be collaboratively led by the Science Council Chair, Professor Sandy Thomas, with close contribution from other Council members as “Work Package Leads” (Work Package 1 & 2 TBC) and from the FSA’s Chief Scientific Adviser, Professor Robin May (Work Package 3).