

FSA Response to the Science Council report on ‘Wider Impacts Beyond Food Safety Risk Assessment’.

1. It has long been the ambition of the FSA Board to be able to consider a broader range of factors (beyond safety) in risk analysis, including animal health and welfare, health and safety, economic impact, environmental impact, trade distortion, impact on consumer choice, socioeconomic factors, consumer perceptions, acceptability and preferences, and the wider interests of consumers in the food system. Decisions on which factors are relevant to the evidence package supporting each risk analysis decision are made jointly by scientists and policymakers at the problem formulation stage of the risk analysis process.
2. Consideration of some factors are mandatory, such as providing economic advice on any measure with a likely impact on business of more than £10m; independent verification for such business-impacting measures; and the documentation and funding of burdens on local authorities. Since November 2023, Environmental Impact Assessments (EIAs) are required to ensure policymaking aligns with Environment Principles. Traditionally, the FSA has also sought evidence of consumer views on contentious decisions to demonstrate its duty of care to the consumer interest.
3. The FSA Strategy sets out how we believe healthier and more sustainable food (as well as safe food) is in the wider consumer interest. Given this ambition, but also the current resource constraints, we asked the Science Council to help us scope the size of the challenge by taking a case study approach to three known products to test how we would approach provision and use of evidence of the impacts (positive or negative) on health and sustainability as well as the food safety risk.
4. We thank the Science Council for a thoughtful and useful report, and for the recommendations in it:

- Recommendation 1. Update FSA internal processes to identify how, where (relative to food and feed safety regulatory assessment) and by whom wider impacts are identified and assessed. Transparency is especially important when considering wider impacts beyond traditional risk assessment to ensure trust in risk management and policy.
- Recommendation 2. Develop an up-to-date map of government policies impacting the food system and dietary patterns and quality, to identify ownership, guide evaluation of wider impacts beyond food safety risk assessment across government and ensure policy coherence.
- Recommendation 3. It is not currently possible to rank or easily compare evidence for wider impacts. The FSA should collaborate with other government departments and agencies to develop guidelines for structured evidence evaluation across impact areas, including evidence sources and quality, use of comparator products and benchmarks, and comparison of options/alternatives.
- Recommendation 4. Develop in collaboration with other government departments a set of criteria for selection of impacts for inclusion in FSA risk management considerations.
- Recommendation 5. Environmental sustainability of production systems for any food product should be viewed as context dependent. Any assessment of sustainability should take appropriate account of waste products, water (use and contamination of fresh and sea water), greenhouse and malodorous gas emissions, soil health, biodiversity and changes in land and marine use and how these might be influenced by the widespread consumption of the food product. Although methodologies for environmental impact assessment, and international and UK environmental standards exist, new metrics and means of applying existing assessments and standards to food standards will be required.

- Recommendation 6. Explore the thorough exploitation of all available data including National Diet and Nutrition Survey (NDNS), and other appropriate data sources to gain better insights into potential nutritional consequences of changing dietary patterns associated with new categories of product, food preparation and cooking practices, retail and media trends.
- Recommendation 7. Use existing data sources to develop a predictive tool (with input from other government departments) with which to better assess the impact of product reformulation on food properties (e.g., to elaborate more nuanced data on food matrix changes and stability; breakdown calorie data from fat, sugar, etc) and unintended impacts on nutrition and health.
- Recommendation 8. Improve application of existing data on how consumer perception of benefit and risk drives eating behaviour, to assist consumer choices in an increasingly complex food environment. It is desirable as a prerequisite to agree working definitions of terms such as “ethical”, “natural”, “processed”, etc.

5. Some of these are already in train. Recommendation 1 points towards the principle that the incorporation of wider impacts into risk analysis should be led by consumer research. In 2022 FSA published [deliberative research into the wider interests of consumers](#) which grounds decisions about what to include at the problem formulation stage.

6. Recommendation 4 proposes that we develop a set of criteria for selection of these impacts in consultation with other Government departments. Some of these are already covered by our statutory obligations. In addition, the Advisory Committee for Social Science has previously provided advice on the selection and weighting of legitimate factors, which has formed part of our internal risk analysis guidance and which is included here at Annex A. Training has been ongoing since 2022 with both policy and science teams to fully embed these principles, and this will continue.

7. We recommend that we begin to address Recommendations 2, 5 and 8 through our research programmes and published Areas of Research Interest in the coming months. Following implementation of Recommendation 2, we may then seek to convene the Government analytical community working on food

policy across 30+ different departments to advance this recommendation more widely.

8. This is because to deliver the other recommendations (Recommendations 3,6,7) would only be possible with significant additional resource and the support of colleagues in DHSC and Defra and the devolved equivalents. Evidence on nutrition and sustainability is provided to Ministers by the department with the appropriate scientific expertise and committees: DHSC oversees nutrition, while Defra handles environmental stewardship and sustainability. Notwithstanding the size of the challenge, the cross-departmental working inherent within the five 'missions' of the new Government provide opportunities for better join-up of regulatory decision making between departments that we are keen to explore.

Annex A - ACSS advice: Other legitimate factors: how should the FSA frame, evaluate and communicate the role of OLFs?

As set out at the [FSA Board meeting in March 2019](#), risk management decisions need to take into account an appropriately broad range of possible impacts in addition to the human health risk assessment. This is standard practice in risk management. The factors which will come into play will differ on a case-by-case basis, taking into account the specific situation and local circumstances e.g. in considering the UK as a whole and/or issues related to individual countries.

Though non-exhaustive, the FSA have identified some common core factors:

- public health, safety and wellbeing;
- wider consumer interests;
- consumer habits, perceptions, acceptability and preferences;
- economic impact;

- technical/feasibility considerations

As well as the core factors above, other factors that may require consideration have been identified by the FSA, including: the coverage and effectiveness of any nonlegislative benchmarks in delivering substantially the same objective as government intervention; political change in trading partners; social economic factors; animal welfare; impact on trade; environmental impact. These factors will vary according to the issue under consideration’.

As the experts in these fields, the Advisory Committee for Social Science was asked by the Chief Scientific Adviser to advise on principles for developing recommendations on legitimate factors to include in complex risk analysis questions

This paper has two aims:

- to set out how evidence on other legitimate factors should be assured; and
- establish mechanisms for ensuring that FSA’s analytical consideration of other legitimate factors within the risk analysis process is guided by the most appropriate high-quality evidence.

Legitimate factors

The criteria for deciding whether a factor should be recommended for inclusion in any risk analysis process could be established by reference to:

- Practice in other countries/assessment systems
- An assessment framework such as APEASE (see below)
- Representations from interest groups, so long as transparent (in terms of who they are, who they represent, and why they consider that they have an interest).

- Consultation with stakeholders, or public survey, if time allows.

Evidence

The types of evidence that would count include:

- public opinion surveys
- scientific data
- economic modelling
- cost benefit analysis
- consensus exercises and public dialogues
- considerations of short and long-term effects

The evidence could include domains identified in the [APEASE](#) criteria e.g. Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Spillover/Side Effects, Equity.

The quality of evidence applied to any of the above types of evidence should be in line, where possible, with standards set for scientific evidence on those direct to human health, or the standards separately specified and made transparent.

The criteria for the circumstances under which such evidence can legitimately be submitted for consideration include:

- As part of an approval dossier submitted by specified groups
- Evidence commissioned by the FSA

- New evidence submitted by a third party (see separate guidance on such evidence developed by the Science Council).
- Evidence submitted in response to a consultation

Risk Analysis

The academic literature concurs that there is no 'one size fits all' model that is universally applicable to every risk. Thus, the final choice of which possible 'legitimate factors' are included in any given risk analysis/risk management consideration will be determined by risk managers, based on the specifics of the risk in question, in discussion with colleagues in Analytics. This paper is designed to help both policymaker and analysts develop the most robust, evidence-based recommendations possible.

The process of deciding the legitimate factors to be included, the type and standard of evidence accepted, and the assessment of the evidence submitted to support them, should all be fully transparent and the evidence published. The weighting of different factors in the final decision is a separate process which should also be fully transparent.

Risk managers should indicate how these factors affect the selection of risk management options and strategies, and the development of resulting standards and guidelines. In doing so, it could be useful to look at some of the questions identified by experts (Renn: Risk Management chapter in Renn (2008) Risk Governance, Earthscan) for assessing risk management options. Risk managers and analysts might ask themselves whether the inclusion of this 'other legitimate factor' will:

- increase the effectiveness and efficiency of risk management options
- minimise external side effects?
- contribute to the overall goal of sustainability?

- helps us decide whether a risk management decision is fair (in terms of burdening people in a fair and equitable manner)?
- helps us decide if a decision is compatible with legal requirements and political programmes?
- helps us decide if a decision is ethically and morally acceptable and is it publicly acceptable?