

General Considerations: Wider impacts beyond food safety risk assessment

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1. The FSA's mission to ensure that "people can trust that the food they buy and eat is safe and what it says it is, and food is healthier and more sustainable" raises consumer interests that are wider than food safety. In 2022 the FSA published research on the 'wider interests' that consumers want to be protected on their behalf (Conners *et al.*, 2022). The research showed that, when making food decisions, as well as needing access to safe, affordable food, the UK public have deep concerns about health and nutrition, ethics and the environment. There is also an abundance of interest in wider impacts in the private sector reflected in investor demands and the growth of environmental, social and governance (ESG) standards. Demands on the food system are growing, resulting in greater complexity. Cons

umers and civil society stakeholders are demanding a more sustainable and more resilient food system. The COVID-19 pandemic and, more recently, conflict in Ukraine had big impacts on food systems in different ways. Decarbonisation, food security and a growing public health crisis associated with poor diets and lifestyles are also likely to grow in importance.

2. Price and the cost of living lead many consumers to make uncomfortable compromises around the 'wider interests' in food that they care about. Industry responds to consumer concerns – recognising price imperatives, and also seeking to differentiate their products through focussing on marketing how their product meets perceived consumer interests around the themes of healthy eating, nutrition, environmental sustainability, and ethics.

3. In addition to broad consumer interests beyond food safety, the FSA has to take account of other factors: government policy, public health agrifood system impacts including economic feasibility, environmental sustainability, broader environmental impacts and trade (FSA Board Paper 19-03-08).

4. Table 1 builds on existing FSA and Codex Alimentarius documents on wider impacts/other legitimate factors and, while not designed to be an exhaustive attempt to capture impacts, it highlights the broad scope of wider impacts, necessitating criteria to identify major impacts. It is noteworthy, that the availability of standard or recognised measures is patchy for many of the proposed impacts. However, this is changing rapidly.

5. Food packaging is of significance because of direct environmental impacts and also because of its importance in protecting food from spoilage and contamination. Packaging has an important role to play in the management of food safety, food quality, shelf life and waste. The three case studies selected did not link directly with considerations of food packaging. However, in consideration of the impacts listed in Table 1, it was agreed that food packaging is a major cross-cutting issue for which wider impacts should be considered.

Table 1. Proposed List of Wider Impact[†] Areas and Sub-Topics of Relevance in Food Regulatory Assessment

Impact Area	Topic	Measures/Standards (if any)	Comments
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Public Health	Nutrition	<p>Impact on intake of nutrients of public health importance.</p> <p>NDNS and other survey data</p>	<p>Concern about intakes of saturated fat, energy, sugar and salt is well founded and backed by strong evidence. The quality and quantity of protein in the diet. The bioavailability of macro and micronutrients in the diet (for novel products, these impacts would likely be captured in the pre-market approval or flagged for later verification/assurance).</p>
Self-care		<p>Support for consumers seeking dietary support for health conditions/special needs.</p>	
Emotional and mental health		<p>Consumer wellbeing and quality of life.</p> <p>Public trust in food.</p>	
Food and nutrient security	NDNS and other survey data		

Agrifood
System

Technical/organisational
feasibility of options

Technical capability
and capacity to
implement risk
management options
and ability to enforce
controls.

Economics*

Cost of
implementing risk
management
options and
distribution of
costs. Impact on
domestic and local
production. The
viability of elements
of the food system
may impact future
food security,
prices, quality and
environmental
sustainability.
Business
sustainability.

Good
Agricultural
and good
manufacturing
practices

Public and private
standards (e.g., Defra
COGAP for Reducing
Ammonia Emissions;
Red tractor producer
standards; BRCGS
Global Food Safety
Standard)

Good practice
standards give
assurances that
appropriate
procedures,
training, measures
and verification are
in place to
safeguard the
health and interests
of consumers from
harm. In the
absence of such
practices, end-
product testing
cannot provide an
acceptable level of
certainty.

Animal health and welfare	<p>e.g., guidelines from WOAAH; RSPCA, etc</p> <p>e.g., WOAAH Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials</p>	<p>British consumers have been among the most vocal about concerns for animal welfare. Historical examples include the size of battery hen cages, veal crates, and facility for animals to graze and feed naturally.</p> <p>AMR in pathogens of human clinical significance is a growing public health concern associated, <i>inter alia</i>, with use of antimicrobial veterinary drugs.</p>
Food/ingredient availability/ security; equity		<p>Food availability, security/affordability is always paramount and ultimately will determine the level of risk tolerance at several levels, including at domestic level. It can also be a driver of food fraud.</p> <p>Are risks, benefits and costs shared equitably?</p>

Sustainability	UN sustainable development goals; MSC seafood standards	Sustainability is a broad term with several dimensions. Suitable metrics for sustainable food systems are being developed.
Worker Safety and Welfare	Public standards (e.g., ISO 34101 for cocoa; ISO 26000:2010; ILO Labour Standards). Private Certification (e.g., Fairtrade ; BRCGS ETRS ; ETI base code)	-

Wider
Consumer
Interests

Labelling and Informed
Choice

FSA Research

FSA Food & You
data

Consumers have a right to information on topics that can have an impact on choice and health. A necessary pre-requisite is the ability to understand the information provided and to derive a benefit from it. Regulators may use a warning label as a means of ensuring consumers make an informed choice for example when sub-groups of consumers may be at risk or where there is developing concern but no evidence of risk. Such approaches are framed by wider government policy.

Taste,
Convenience,
variety,
durability

Waste, value for money

Eating pleasure,
consumer
satisfaction,
affordability and
health.

Cultural and
religious
requirements

e.g., Halal and Kosher
regulations

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Trust

FSA Research

FSA Food & You data

Misleading, false or conflicting information may lead to consumer mistrust and be harmful to the goals of achieving a safe, affordable, healthy and sustainable diet. Information that could disrupt the marketplace or lead to increased prices may not be in the interests of consumers.

Perceived risks
FSA Research
FSA Food & You data

Many factors can contribute to risk perception among consumers. Perceived risk is not necessarily the same as scientifically measured risk but is “real” for consumers. The factors contributing to perceived risk are many and may be subjective in nature. For example, ethnic background and belief systems; religious belief; media attention. Perceived risk may be important, even dominant, in driving consumer expectations, but unfounded perceptions could also be harmful if it drives unhealthy or unaffordable behaviours.

Trade	Harmonisation and non-technical barriers to trade	WTO Rules (e.g., SPS measures)	Trade is covered by WTO rules including the GATT which evolves over time. WTO encourages members to base standards on three recognised international standard-setting bodies: the Codex Alimentarius Commission for food safety; the IPPC for plant health; and the WOAHP for animal health and welfare and zoonoses.
Environment	Carbon dioxide	e.g., ISO 14040 series and other standards Private certification bodies (e.g., RSPO; Rainforest Alliance)	Including deforestation (terrestrial and marine); land use; Life-cycle analysis; food losses and waste.
Water	e.g., ISO 14046 FAO best practice recommendations	Water footprints and efficiency of use; local water resource impacts.	

Biodiversity, wildlife and risks to wider environment	e.g., OECD Policy papers/ test protocols; Nagoya Protocol	Impact on natural environments; pollinator health, water quality and availability; plant health. Introduction and impact of non-native species (risks and benefits).
Other emissions	e.g., Defra COGAP for Reducing Ammonia Emissions	For example, methane and greenhouse gases (other than CO ₂); toxic and malodourous gases (e.g., ammonia); water discharges of nitrogen, phosphorus; microorganisms; covering both environmental damage and “amenity” impacts for citizens.

†This list includes the impacts already identified by the FSA (FSA Board Paper 19-03-08) and the other legitimate factors identified by the Codex Alimentarius Commission (FAO and WHO, 2022; FAO and WHO, 2023b). Codex Alimentarius is mainly focused on fair trade considerations and labelling.

*Economics connects all proposed impact areas as a means of measuring and comparing impacts. Thus, the disciplines of health, food, environmental, public finance economics, etc may all be involved.

Abbreviations

AMR: Antimicrobial Resistance; BRCGS ETRS (BRCGS Ethical Trade and Responsible Sourcing Standard; Defra COGAP: Department for Environment, Food & Rural Affairs Code of Good Agricultural Practice; ETI : Ethical Trading Initiative; GATT: General Agreement on Tariffs and Trade; ILO: International Labour Organisation; IPPC: International Plant Protection Convention; ISO: International Standards Organisation; MSC: Marine Stewardship Council; NDNS: National Diet and Nutrition Survey; OECD: Organisation for Economic Co-operation and Development; RSPCA: Royal Society for the Prevention of Cruelty to Animals; SPS measures: Sanitary and Phytosanitary Measures; WOA: World Organisation for Animal Health (formerly known as OIE, *Office International des Epizooties*); WTO: World Trade Organisation.

Definitions

Sustainability: The FAO (FAO, 2018) defines a sustainable food system as delivering “food security and nutrition for all in such a way that the economic, social and environmental bases to generate food security and nutrition for future generations are not compromised. This means that it is profitable throughout; it has broad-based benefits to society; and it has a positive or neutral impact on the natural environment”.

Food Security: There are many definitions of food security within different contexts (House of Commons, 2023). The FAO (see FAO.org) definition states “food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life”.

6. The objectives of this project were:

1. to identify potential wider impacts beyond food safety risks;
2. assess the availability of evidence on such impacts; and
3. propose ways in which such impacts can be evaluated systematically.

7. This paper provides a background to the general considerations for addressing wider impacts beyond risk assessment, as captured in existing FSA processes and other government documents.

Legislation and government guidance

8. Section 23 of the Food Standards Act (1999) provides for “consideration of objectives, risks, costs and benefits, etc” within the general provisions relating to the functions of the FSA. This entails taking into account “the nature and

magnitude of any risks to public health, or other risks, which are relevant to the decision (including uncertainty as to the adequacy or reliability of the available information) (Subsection a) and the likely costs and benefits of the exercise or non-exercise of the power or its exercise in any manner which the agency is considering (Subsection b)”.

9. Several government documents provide guidance on evaluation and appraisal. They include HM Treasury publications the Green Book (2022) and the Magenta Book (2020). These are guidance documents pointing to best practice in applying a range of methodologies but do not have statutory authority and are not legally binding.

10. In line with government policy on decarbonisation, a supplementary green book guidance document is available on the valuation of energy use and greenhouse gas emissions (Department for Energy Security and Net Zero, 2023). A growing number of documents are becoming available on the evaluation of environmental impacts (e.g., Enabling a Natural Capital Approach Guidance (ENCA), Defra, 2023a; Environmental Principles Policy Statement, Defra, 2023b). While the expertise to conduct evaluation of environmental impacts does not reside within the FSA, the criteria for performing and overseeing such evaluations are becoming clearer and should facilitate a consistent methodological approach.

11. The Better Regulation Framework (2023) (BRF) is also a guidance document. The BRF is primarily aimed at regulatory provisions made by government ministers. However, independent regulators are recommended to follow the framework where possible. Regulatory provisions for operational, day-to-day conduct of regulators, including authorisations of regulatory products, are excluded; the main focus being on new legislation and new policy. The purpose of the BRF is “to ensure that government regulation is proportionate and is used only where alternative, non-regulatory approaches, will either not achieve the desired policy outcomes or will achieve them at disproportionate cost”.

12. Guidance on practices that may mislead the consumer (previously covered by an Office of Fair-Trading report; OFT, 2008) has recently been updated by the Digital Markets, Consumers and Competition Act 2024. The Act provides definitions of unfair practices and describes misleading actions, as well as misleading omissions. According to the Act a misleading action occurs when a practice involves the provision of false or misleading information relating to a product, or there is an overall presentation that is likely to deceive the average consumer about the product, or any marketing which creates confusion, or is likely to create confusion. Misleading information includes reference to

information which, although true, is presented in a misleading way. Material omissions occur when information is omitted that the average consumer needs to take an informed decision. The Act lists practices that are considered unfair in all circumstances, including falsely claiming that a product complies with or has been approved or authorised by a public or private body; publishing consumer reviews in a misleading way (or reviews that are fake); and falsely claiming that a product is able to- prevent or treat disease; restore, correct or modify a physiological function, or modify a person's appearance. Enforcement of the Act is the duty of local authorities and the Competitions and Markets Authority. Advertising claims are dealt with by the Advertising Standards Authority. Information on labels is regulated by the Department for Environment, Food and Rural Affairs (Defra). Additional references to the consideration of wider impacts are available in international trade agreements, in retained EU Law and in the scientific literature (Annex 1).

Current FSA Approach

13. The term generally applied by regulatory agencies in consideration of wider impacts beyond risk assessment is "other legitimate factors". The FSA has several internal risk analysis documents that allow other legitimate factors to be taken into account in the delivery of proportionate protection to consumers. The categories of other legitimate factors documented in 2019 FSA Board paper (19-03-08), are divided into those currently handled by the FSA (economic impact; wider consumer interests; consumer habits, perceptions, acceptability and preferences; impact on trade (partial); cost of carbon emissions and food waste) and factors where expertise is not available internally (nutrition; impact on emotional and mental health; technical and feasibility considerations; impact on trade, including impact on public confidence in UK food; animal welfare; broader environmental implications).

14. More useful is the FSA classification of core and issue-specific factors. Core factors are classified as public health, safety and wellbeing; wider consumer interests; consumer habits, perceptions, acceptability and preference; economic impact; and technical/feasibility. Issue-specific factors are: potential of non-legislative approaches; political change in trading partners; socio-economic factors; animal welfare; impact on trade; environmental impact.

15. Evidence on other legitimate factors (FSA Board paper, 19-03-08) may be gathered as part of the risk analysis process prior to decisions on risk management (Fig.1). As consideration of health risks would always have primacy in risk analysis, the assembly of evidence for wider impacts is secondary to

assuring consumer health is protected.

16. The FSA recognizes that other legitimate factors depend on context and there may be a need to take account of the UK as a whole, as well as issues that may relate to individual home nations.

17. While these documents outline the need to consider other legitimate factors, there is no internal FSA guidance on their evaluation.

Figure 1: Food Standards Agency Risk Analysis Process