ENHANCING THE FSANZ NUTRITION RISK ASSESSMENT FRAMEWORK TO SUPPORT BROADER PUBLIC HEALTH OBJECTIVES

A report by the FSANZ nutrition risk assessment review panel:

Emeritus Professor Linda C Tapsell AM PhD FDA FNSA DFASN

Dr Moez Sanaa DVM PhD

Steven J Wearne OBE FIAFoST

ENHANCING THE FSANZ NUTRITION RISK ASSESSMENT FRAMEWORK TO SUPPORT BROADER PUBLIC HEALTH OBJECTIVES

Table of Contents

INTRODUCTION: SCOPE AND PURPOSE OF THIS REVIEW 4

PART I: CURRENT PERSPECTIVES 10

CHAPTER 1: THE OPERATING AND POLICY ENVIRONMENT FOR FSANZ AND ITS NUTRITION RISK ASSESSMENT ACTIVITIES 11

CHAPTER 2: A CRITICAL APPRAISAL OF THE CURRENT APPROACH TAKEN BY FSANZ TO NUTRITION RISK ASSESSMENT 20

CHAPTER 3: GLOBAL BEST PRACTICES IN NUTRITION RISK ASSESSMENT 34

PART II: KEY CHALLENGES AND OPPORTUNITIES FOR NUTRITION RISK ASSESSMENT 57

CHAPTER 4: FOOD CATEGORIZATION 58

CHAPTER 5: NATIONAL NUTRITION SURVEYS 80

PART III: BUILDING A BLUEPRINT FOR PURPOSIVE FUTURE NUTRITION RISK ASSESSMENT 94

CHAPTER 6: FROM RISK ANALYSIS TO RISK GOVERNANCE: EVOLVING FSANZ NUTRITION RISK ASSESSMENT FOR DECISION-CENTRED AND ADAPTIVE POLICYMAKING 95

RECOMMENDATIONS OF THE FSANZ NUTRITION RISK ASSESSMENT REVIEW PANEL 110

PART IV: ILLUSTRATIVE APPLICATIONS OF THE PROPOSED APPROACH 118

Case study 1: Problem definition for the compositional arm of a future proposal to addressing key issues relating to commercial foods for infants and young children 119

Case Study 2. Ultra-Processed Foods (UPFs): Problem Formulation, Competing Mechanisms, and Implications for Risk Governance 128

Case Study 3. D-Allulose (A1247): An Integrated Risk Assessment and Risk Governance Perspective for Novel Food Approval **149**

GLOSSARY **159**

ACKNOWLEDGEMENTS **161**

INTRODUCTION: SCOPE AND PURPOSE OF THIS REVIEW

0.1 Background

Food Standards Australia New Zealand (FSANZ) has developed and adopted a Risk Assessment Framework for food which is designed to assess and manage risks to public health and safety related to the consumption of food. The current approach and processes used by FSANZ for nutrition risk assessment form part of this Framework.

The approach taken by FSANZ to nutrition risk assessment has evolved in recent years from a former focus on classical aspects of nutrition such as micronutrient excess or deficiency, to a broader public health approach. This shift responds to a number of drivers, including:

- innovations in nutritive substances that have demonstrated beneficial health effects; and
- the increasing prevalence on non-communicable diseases (NCDs) such as diabetes and obesity.

While FSANZ maintains a systematic approach to evidence retrieval and evaluation in its nutrition risk assessment, it has noted that the approaches and principles for nutrition risk assessment in response to these drivers are less well developed when compared to other risk assessment domains such as toxicology.

FSANZ has concluded it is timely to conduct a benchmarking process to enhance its framework for nutrition risk assessment, to support broader public health objectives. It has therefore convened an independent panel to conduct a nutrition risk assessment review.

0.2 Aims of the review

The aims of this review are to assess whether the current FSANZ nutrition risk assessment methodology:

- reflects international best practice;
- adequately captures long-term public health impacts, particularly in the context of changing food environments; and
- can be enhanced to better manage risks related to chronic, preventable NCDs within the current regulatory environment.

0.3 Scope of the FSANZ nutrition risk assessment review

The review has had regard to the operating environment established for FSANZ by the *Food Standards Australia New Zealand Act 1991* (Federal Register of Legislation 2024) and the policy environment within which FSANZ operates (see Chapter 1 for further discussion).

The following key areas are within the scope set by FSANZ for this review:

- Global best practices. Reviewing international best practice in nutrition risk assessment and the assessment of nutrient-related hazards associated with long-term public health outcomes and associated chronic disease.
- Scientific evidence processing and integration. Reviewing the extent to which current nutrition risk assessment methodologies incorporate evidence on chronic disease, dietary patterns and nutrient-related hazards.
- Long-term health risks. Investigating how nutrition risk assessment methodology, in terms of the potential effects of cumulative and sustained dietary exposures, currently addresses long-term public health outcomes.
- Risk communication. Assessing how long-term risks and chronic disease impacts are communicated to the public, policymakers, and other stakeholders.

The following areas are outside the scope of this review:

- The scope allows for referencing of existing legislation or ministerial policy guidance to inform recommendations, but not the setting or changing of legislation or policies.
- Policy advocacy and consideration of enforcement and implementation of food regulation.
- Large scale changes to the risk analysis framework, recognising the review's focus on nutritional risk assessment.

The review will consider the application of nutrition risk assessment to products within the scope of the FSANZ Food Standards Code. In this regard, the panel notes that in Australia, a product intended for consumption is regulated either as a food by FSANZ, or as a therapeutic good by the Therapeutic Goods Administration (TGA). As a result, such products may fall under the special purpose food category or be classified as listed medicines (lower-risk therapeutics). Where products sit at the food–medicine interface, the TGA determines the appropriate regulatory pathway. While a single ingredient (such as caffeine) may be permitted in both foods and medicines, several factors influence the regulatory classification of the final product. Such factors include the product's ingredients, marketing claims, and how it is presented including the dosage form - pill, food bar, powder etc.

0.4 What is safe and nutritious food?

FSANZ has supported the broad and inclusive approach taken by the panel to its review, recognising that nutrition risk assessment plays a critical role in informing and fulfilling policy objectives. FSANZ has noted that, currently, their nutrition risk assessment questions are designed to directly consider any relevant public health and nutrition policy, as outlined in the Ministerial Policy Guidelines. Looking ahead, and subject to potential amendments to the FSANZ Act, they foresee that the scope of these 'policy questions' may expand to include areas more directly aligned with reducing diet-related disease and addressing health inequities.

Accordingly, the panel has sought to describe in plain terms the primary problem it is seeking to address, for both its own benefits and for those of its interlocutors.

In doing so, the panel has taken an epistemological approach to food and nutrition, critically considering the nature, scope, and sources of knowledge about food and nutrition, and the processes that shape how the scientific and regulatory community has come to know, understand, and justify beliefs about food, nutrition, and eating practices. Within this broad question, the remit of the panel is limited to the science of food consumption and health outcomes.

The panel reconfirms the importance of understanding the effects of individual nutrients or dietary components on specific biological markers of human health, as this continues to form a cornerstone of nutrition research. However, a reductionist approach which sees food simply as a formulation of nutrients and other dietary components may not fully capture the complexity of how foods and dietary patterns impact on health. The panel has therefore taken a holistic view that drives it to consider not only how regulators determine whether any constituent of food is safe in isolation, but how they then determine the cumulative effects of food trends and innovation on the diet as a whole.

For the panel, any consideration of food starts with its original forms from nature. These provide the reference point, and the Australian and New Zealand dietary guidelines, which identify the components of a healthy diet in terms of basic food groups and commodities, are the anchor. The panel proposes that food is about more than formulation or function. For example, the recent report from the UK Scientific Advisory Committee on Nutrition on plant-based alternatives to cows' milk, which is referenced in Chapter 3 of this report, notes that the nutrition content of these products varies widely, seemingly in the absence of any sense of a food standard that needs to be achieved, so leading to a category of products that mimic a traditional food and may be able to fulfil a similar function while nutritionally being very different from that traditional food.

The primary problem the panel has identified is therefore: "How do risk assessment and allied approaches used by regulatory authorities identify and characterize the

chronic disease risks associated with different and changing dietary patterns, and inform the selection of appropriate risk management and mitigation strategies?"

This primary problem will then allow specific questions to be framed for nutrition risk assessment, such as:

- what part do individual foods play in poor dietary patterns?
- what part do new ingredients and food processes play in producing foods seen as deleterious to healthy eating patterns?

This has led the panel to propose a blueprint for future nutrition risk assessment which facilitates consideration of these questions (see Chapter 6).

Within this blueprint, the panel envisages an approach in which FSANZ sets out the context or framework for the risk assessment, following which issues relating to problem formulation are discussed with external stakeholders through a consultative and publicly transparent process that is distinct from and in addition to the statutory consultation process.

This would aim to socialise the issues involved and help stakeholders to understand the context and framing of the issue, which would remain the responsibility of FSANZ. While this approach would not be needed for every issue, it should be incorporated into existing practice when dealing with major, novel or contentious issues.

The panel sees post-market monitoring as an essential part of assessing changes in dietary patterns and possible impacts on NCD risks. The first stage in risk assessment - problem formulation - then becomes even more important as, among other things, it will identify the hypotheses that post-market monitoring should test.

0.5 Parallel reviews and relevant work by others

There is a significant current interest in nutrition and public policy that reaches beyond FSANZ. Other reviews are currently underway whose conclusions and recommendations may impact whether and how FSANZ implements the recommendations in this report. In particular:

- The Australian Dietary Guidelines (NHMRC 2013), published in 2013, are currently under review.
- The World Health Organization (WHO) is undertaking work with the objective of developing guidance in two parts: an operational definition of ultra-processed foods; and a WHO guideline on consumption of ultra-processed foods.

The panel is aware of these reviews but has not attempted in its work or in this report to prejudge their potential outputs. The panel is content for its review and associated recommendations to stand on their own merits.

0.6 The structure of this report

Part I of this report provides the panel's perspectives on the framing of, and current approaches to, nutrition risk assessment.

The panel has acknowledged that it must have due regard to the operating environment for FSANZ established in law, and the policy environment for FSANZ established by ministerial policy guidance. Chapter 1 sets out the panel's assessment of this environment, and the extent to which it sets boundaries for the issues the review may consider and the recommendations the panel may make.

The panel has noted the transparency of the current processes and approaches that FSANZ takes to nutrition risk assessment, and the earlier review of FSANZ nutrition risk assessment undertaken by Angelika Tritscher in 2011 (FSANZ 2017) together with FSANZ's response to that review's recommendations. This has informed the panel's critical appraisal of the current processes and approaches, which is set out in Chapter 2.

The panel has noted the aims of the review in relation to capturing the long-term public health impacts of changing food environments and dietary patterns, and using these insights to better manage risks related to chronic preventable diseases such as diabetes, obesity and cardiovascular disease within the current regulatory environment. The panel has tested through discussion with other national food regulatory agencies and with a relevant multilateral body the extent to which these aims are being realised and modelled elsewhere, providing a benchmark for both the current nutrition risk assessment approach of FSANZ and the aspirations it has set out in the terms of reference for this review. These discussions are detailed in Chapter 3, together with the panel's conclusions regarding benchmarking and opportunities to enhance the approach of FSANZ to nutrition risk assessment.

The changing nature of food and the increasing pace of food innovation create new challenges and opportunities for nutrition risk assessment. Part II of this report explores the panel's perspectives on key challenges and opportunities.

In chapter 4, the panel considers the challenges posed by the increasing salience of process-based food categorisation. In chapter 5, the panel considers the role of data and analysis from national dietary surveys in nutrition risk assessment, the challenges inherent in making the most effective use of this valuable resource, and also how regulators might track changes in the composition of food and in dietary patterns in the period between successive national dietary surveys, which will be key to a future approach that incorporates post-market monitoring.

Part III integrates the conclusions of the preceding chapters and, from these, builds a blueprint for purposive future nutrition risk assessment.

Risk assessment – the subject of this review – does not exist alone but forms one part of the current risk analysis paradigm, alongside risk management and risk communication. The panel explores the interrelationships between risk assessment and the other elements of risk analysis in Chapter 6, centred on the concept that risk assessment must always be purposive, addressing the questions and issues identified in prior problem formulation.

The panel also proposes in Chapter 6 a blueprint for future FSANZ nutrition risk assessment, building on its benchmarking of the current approaches and processes of FSANZ for nutrition risk assessment against international best practice, its identification of key challenges for nutrition risk assessment, and a renewed role for risk assessment within the risk analysis paradigm.

This part of the report closes with a list of the panel's recommendations.

Part IV of the report provides supplementary material in the form of case studies on topics agreed between the panel and the FSANZ Executive, to illustrate the application of key elements of the blueprint that the panel proposes.

References and footnotes for Introduction

Federal Register of Legislation (2024) *Food Standards Australia New Zealand Act 1991*, No. 118. https://www.legislation.gov.au/C2004A04193/latest/text. Accessed 14 November 2025. Note: The FSANZ Act is currently under review by the Commonwealth Department of Health. While the outcomes of the review should not be pre-empted, it may be considered in the context of the review.

FSANZ (Food Standards Australia New Zealand) (2017) External peer review of FSANZ risk assessment practices and procedures, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/publications/External-Peer-Review-of-FSANZ-Risk-Assessment-Practices-and-Procedures. Accessed 14 November 2025.

NHMRC (National Health and Medical Research Council) (2013) Australian Dietary Guidelines. National Health and Medical Research Council, Canberra. https://www.health.gov.au/sites/default/files/australian-dietary-guidelines.pdf

PART I: CURRENT PERSPECTIVES

CHAPTER 1: THE OPERATING AND POLICY ENVIRONMENT FOR FSANZ AND ITS NUTRITION RISK ASSESSMENT ACTIVITIES

As stated in the introduction, the panel has had regard to the framework set by the operating environment for FSANZ established in law, primarily the *Food Standards Australia New Zealand Act 1991* (the Act) (Federal Register of Legislation 2024), and the policy environment for FSANZ established by ministerial policy guidance.

1.1 The operating environment of FSANZ

FSANZ is a creature of statute. It was established by, and its functions and powers are set out in, the Act.

The Act has been in place for over 30 years, with relatively few amendments in that time. Food Ministers have recognised the importance of the Act within the food regulatory system and have endorsed the need for a holistic review of the Act. The terms of reference of that review include a comprehensive examination of the effectiveness of the Act and the associated operations and responsibilities of FSANZ.

To inform the review of the Act, which continues at the time of writing this report, an impact analysis has been published. This impact analysis provides context for potential legislative changes, including details on a set of policy problems. Of the four policy problems identified, the most relevant to this review are:

- The purpose and objectives of FSANZ are not clear. Inconsistencies in how key terms are defined in the Act contribute to uncertainty about the purpose of standard-setting and how regulatory measures can be used to manage short- and long-term health risks.
- Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible. The Act is highly prescriptive around how variations to food standards can be made and creates the environment in which FSANZ is forced to prioritize applications (which are subject to legislated timeframes) over proposals or other work.

Regarding the purpose and objectives of FSANZ, the impact analysis cites the views of "many stakeholders" who have indicated that the terms 'public health protection' and 'public health and safety' used in the object of the Act (Section 3) and the objectives of FSANZ (section 18) are poorly defined in the legislation, and that this creates ambiguity, as these terms could refer solely to preventing foodborne illness or injury, primarily in the acute, post-consumption period, or could include mitigation of long-term health impacts, including through the prevention of non-communicable diseases (NCDs).

In practice, clarity has been provided (as set out in the following section) in subsequent ministerial guidelines. These indicate that public health and safety in relation to food refers to all those aspects of food consumption that could adversely affect the general population or a particular community's health either in the short term or long term, including preventable diet-related disease, illness and disability as well as acute food safety concerns. This definition was reaffirmed by Ministers in late 2022.

Nevertheless, the impact analysis identifies and analyses the option of amending and aligning the FSANZ Act to clarify that the definition of 'protecting public health and safety' encapsulates both acute and long-term health elements.

1.2 The policy environment of FSANZ

The Australia and New Zealand Food Regulation System, of which Food Standards Australia New Zealand (FSANZ) is a key part, has as its strategic outcomes:

- to protect the health and safety of consumers by reducing risks related to food;
- to enable consumers to make informed choices about food by ensuring that they have sufficient information and by preventing them from being misled;
- to support public health objectives by promoting healthy food choices, maintaining and enhancing the nutritional qualities of food and responding to specific public health issues; and
- to enable the existence of a strong, sustainable food industry to assist in achieving a diverse, affordable food supply and also for the general economic benefit of Australia and New Zealand.

In pursuing these outcomes, the overriding priority will always be protecting public health and safety (Australian Government 2017). The panel has noted the communiqué from the Food Ministers' Meeting on 14 November 2025 (Australian Government 2025a) which provides further insight into the interrelationship between these outcomes, noting that all four contribute to national productivity and economic performance. In particular, "Ministers acknowledged that a well-designed and efficient regulatory system provides a predictable environment for businesses to thrive, enter new markets and innovate". This is aligned with the OECD orthodoxy (OECD n.d.) that governments have a crucial role to play in fostering innovation while ensuring the right guardrails are in place to protect people, and that this requires a forward-looking perspective that is agile, technology-neutral and risk-based to match the expectations of contemporary society.

Within the Australia and New Zealand Food Regulation System, FSANZ is recognised as a statutory authority having sole competence for the development of food standards based on scientific and technical criteria. The policy direction for the work of FSANZ is set by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum), which comprises the Ministers from all Australian States and Territories,

as well as the Australian and New Zealand Governments. The Forum sets the policy; FSANZ sets standards consistent with this policy.

Ministerial Statements provide clarity through their strong and consistent direction, which acknowledges that "Public health and safety in relation to food [i.e. that which FSANZ is charged by statute with protecting] refers to all those aspects of food consumption that could adversely affect the general population or a particular community's health either in the short term or long term, including preventable diet-related disease, illness and disability as well as acute food safety concerns. The work of FSANZ complements the roles of other key public health agencies within Australia and New Zealand. FSANZ takes into consideration both long-term health impacts and immediate health risks in the development and review of food regulatory measures" (Legislative and Governance Forum on Food Regulation 2013).

This statement in permissive in terms of the extent to which food standards development may take into account preventable diet-related disease. The policy tools that are available within the food regulation system to address these diseases are described in the 2017 Overarching Strategic Statement. This states that "the primary goal of the regulatory system is to protect the health and safety of consumers of food – in other words, to protect Australians and New Zealanders from preventable health risks associated with the consumption of food. This means:

- helping to prevent people becoming sick or dying as the result of the consumption of unsafe food; and
- providing consumers with information so that they can choose appropriate food and remain healthy over time."

The 2017 Overarching Strategic Statement also recognizes that the Food Regulatory System is increasingly called on to play a role in supporting public health objectives such as obesity prevention strategies, and that it would be increasingly important to clearly identify and prioritize the role of food regulation in this broader context. To this end, in April 2017 the Forum agreed Food Regulation priorities for 2017 - 2021. One of three priority areas agreed by Ministers for strengthening the food regulation system was: "to support the public health objectives to reduce chronic disease related to overweight and obesity. This will include evaluating the effectiveness of existing initiatives and identify potential new initiatives, such as how the food regulation system can facilitate healthy food choices and positively influence the food environment."

The strategic direction for the Food Regulatory System was confirmed by the Food Ministers' Meeting in January 2025, when they endorsed the Strategic Plan for the System for 2025-2028 (Australian Government 2025b). The Strategic Plan maintains a focus on the effective regulation of food safety and on evidence-based consumer information that contributes to coordinated, multi-sectoral and population-wide strategies to improve diets. Its objective of a healthy food supply also acknowledges

that the food supply has a role to play in supporting healthy dietary patterns, and should align with national dietary guidelines.

Other Ministerial policy guidance relevant to nutrition risk assessment covers:

- the development and implementation of front of pack nutrition labelling which, *inter alia*, should aim to:
  - guide consumer choice by: enabling direct comparison between individual foods that, within the overall diet, may contribute to the risk factors of various diet related chronic diseases; and increasing awareness of foods that, within the overall diet, may contribute positively or negatively to the risk factors of diet related chronic diseases.
  - be consistent with other health strategies and guidelines by: supporting and being consistent with the objectives of programs and strategies designed to reduce the risk of diet related chronic diseases; guiding consumers to the selection of foods consistent with the Australia and New Zealand dietary guidelines; and supporting and being consistent with the Australia and New Zealand dietary guidelines and Nutrient Reference Values
  - affect the environment in which consumers make choices by: contributing to the creation of a supportive environment that can guide consumer choice towards healthier foods within the overall diet; and providing incentive for improvements to the healthiness of the food supply (ANZFRMC 2009a).
- fortification (including mandatory fortification) of food with vitamins and minerals, and the composition and labelling of Special Purpose Foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups, which should "be based on risk analysis using the best available scientific evidence" (ANZFRMC 2009b; ANZFRMC 2009c).
- the composition of infant formula products, the regulation of which "should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants" with, in particular, pre-market assessment required for "any substance proposed to be used in infant formula and follow-on formula that does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology" (ANZFRMC 2025).
- novel foods, where FSANZ was charged with raising a proposal to review Standard 1.5.1 of the Australia New Zealand Food Standards Code which would consider, *inter alia*, "the use of a decision tree approach to determine if an application/premarket assessment is required should be considered. A decision tree should provide industry and enforcement agencies with clear guidance in such a determination", with the purpose of the decision tree to ensure a "Level of assessment to be commensurate with level of risk" (ANZFRMC 2003).
- the regulatory management of caffeine in the food supply, which should "be based on risk analysis ensuring consideration of the general population and

taking into account vulnerable population groups including children, adolescents, pregnant and lactating women and caffeine sensitive consumers" (ANZFRMC 2014).

1.3 A focus on food labelling

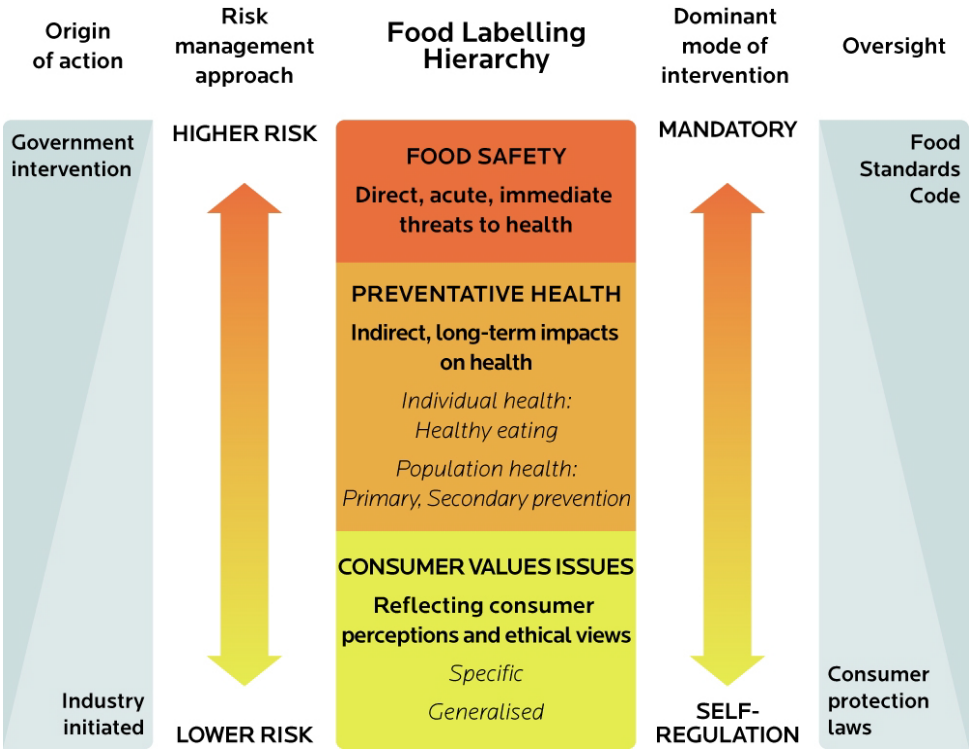
As highlighted above, the 2017 Overarching Strategic Statement identifies the primary goal of the regulatory system "is to protect the health and safety of consumers of food", which includes "providing consumers with information so that they can choose appropriate food and remain healthy over time."

Further direction in relation to food labelling is provided in 2020 policy guidance (ANZFRMC 2020), which states that the objective of nutrition food labelling is to "…provide adequate information to enable consumers to identify foods that do and do not contribute to healthy dietary patterns recommended in the Dietary Guidelines" (MoH 2020; NHMRC 2013).

The Strategic Plan 2025-2028 has, as two of its aims, that the food supply aligns with national dietary guidelines and that food labelling provides clear and accurate information for consumers to make safe and healthy choices.

The Australian Dietary Guidelines use a broad food categorization approach to drawing distinctions between foods that do and do not contribute to healthy dietary patterns, based either on food groups (e.g. vegetables; fruit) or nutrient composition (i.e. foods containing saturated fat, added salt, added sugars and alcohol). The New Zealand Dietary Guidelines similarly focus on eating a variety of nutritious foods every day, describing an eating pattern that is largely plant-based, and allows for moderate amounts of animal-based foods (eggs, dairy, poultry, seafood) and small amounts of red meat, thereby focusing on consumption of 'whole and less processed' nutrient-dense foods while limiting 'highly processed foods' with saturated fats, added sugar and salt.

In terms of food labelling and information, the 2020 policy guidance states that "Information that enables consumers to identify foods that contribute to healthy dietary patterns recommended in the Dietary Guidelines is a public health priority and therefore sits towards the mandatory end of the 'dominant mode of intervention' within the preventative health section of the Food Labelling Hierarchy". The panel notes the term "towards the mandatory end" places nutrition labelling in a different position in this spectrum from food safety labelling, which is firmly at the mandatory end of the spectrum, as shown in the figure below which is annexed to the 2020 policy guidance.



It is the experience of the panel, reinforced by discussions with FSANZ Executive colleagues over the course of the preparation of this report, that in practice, labelling tends to be considered at the end of the regulatory process as a mechanism to mitigate the residual risks once other agreed risk management interventions have been made. This makes it an intervention of last resort, as it provides consumers with considerable agency and responsibility to manage risks they might otherwise face related to consumption of the labelled food.

In the view of the panel, this introduces some asymmetry into the anticipated actions of the Regulation System in relation to chemical and biological risks on the one hand, and in relation to nutrition risks on the other hand. In the former case, there is a presumption of government intervention using regulatory tools to prevent consumption of food that is unsafe as the result of chemical or biological contamination. In the latter case, there is a presumption that consumers should enjoy a greater degree of agency in relation to mitigation of the nutrition risks they may encounter, with the role of the Regulation System largely limited to the provision of information to facilitate healthy food choices by consumers.

1.4 Conclusions

The panel notes the direction set out in policy guidance, that the increasing prevalence of NCDs such as obesity and diabetes, as well as nutrition-related food innovations, now demands more holistic public health approaches. Successive ministerial policy

statements have made it clear that the study of the interaction between the diet and NCDs, and related policy advice, is within the scope of FSANZ.

By extension, the panel strongly believes that nutrition risk assessment conducted by FSANZ should include within its scope a holistic consideration of how food innovations and changes in food composition play a role in changing dietary patterns as this is the mechanism by which those innovations and changes may influence NCDs risk. Given that risk assessment should always be purposive, the review has included the issue of whether and how nutrition risk assessment policy and practice in FSANZ may be enhanced so as to generate outputs that can support the identification and selection of the most appropriate interventions to reduce the burden of NCDs, consistent with Food Regulation priorities.

References for Chapter 1

ANZFRMC (Australia and New Zealand Food Regulation Ministerial Council) (2009a) Front of Pack Labelling Policy Statement, Australia and New Zealand Food Regulation Ministerial Council, Canberra. https://www.foodregulation.gov.au/sites/default/files/2023-08/policy-statement-on-front-of-pack-labelling.pdf. Accessed 14 November 2025.

ANZFRMC (2009b) Policy guideline for the fortification of foods with vitamins and minerals, Australia and New Zealand Food Regulation Ministerial Council, Canberra. https://www.foodregulation.gov.au/resources/publications/policy-guideline-fortification-foods-vitamins-and-minerals. Accessed 13 November 2025.

ANZFRMC (2009c) Policy Guideline on the intent of Part 2.9 of the Food Standards Code – Special Purpose Food, Australia and New Zealand Food Regulation Ministerial Council, Canberra. https://www.foodregulation.gov.au/sites/default/files/2023-08/policy-guideline-on-intent-of-part-2-9-of-the-food-standards-code-special-purpose-foods.pdf. Accessed 13 November 2025.

ANZFRMC (2025) Regulation of infant formula products, Australia and New Zealand Food Regulation Ministerial Council, Canberra. https://www.foodregulation.gov.au/sites/default/files/2025-01/policy-guideline-on-infant-formula-products.pdf. Accessed 13 November 2025.

ANZFRMC (2003) Ministerial Council policy guidelines on novel foods, Australia and New Zealand Food Regulation Ministerial Council, Canberra. https://www.foodregulation.gov.au/sites/default/files/2023-08/policy-guideline-on-novel-foods.pdf. Accessed 13 November 2025.

ANZFRMC (2014) Ministerial Policy Guideline: Regulatory management of caffeine in the food supply, Australia and New Zealand Food Regulation Ministerial Council, Canberra. https://www.foodregulation.gov.au/sites/default/files/2023-

08%20%20/policy-guideline-on-the-addition-of-caffeine-to-foods.pdf. Accessed 13 November 2025.

ANZFRMC (2020) Policy guideline on food labelling to support consumer to make informed healthy food choices, Australia and New Zealand Food Regulation Ministerial Council, Canberra. https://www.foodregulation.gov.au/sites/default/files/2023-09/policy-guideline-on-food-labelling-to-support-consumers-to-make-informed-healthy-choices.pdf. Accessed 12 November 2025.

Australian Government (2017) Overarching strategic statement for the food regulatory system, Australian Government, Canberra. https://www.foodregulation.gov.au/resources/publications/overarching-strategic-statement-food-regulatory-system. Accessed 8 November 2025.

Australian Government (2025a) Food Ministers' Meeting communiqué – 14 November 2025, Australian Government, Canberra. https://www.foodregulation.gov.au/food-ministers-meeting-communique-14-november-2025. Accessed 20 January 2026.

Australian Government (2025b) Strategic Plan 2025-2028. https://www.foodregulation.gov.au/resources/publications/strategic-plan-2025-2028. Accessed 17 April 2026.

Federal Register of Legislation (2024) *Food Standards Australia New Zealand Act 1991*, No. 118. https://www.legislation.gov.au/C2004A04193/latest/downloads. Accessed 10 November 2025.

Legislative and Governance Forum on Food Regulation (2013) The interpretation of public health and safety in developing, reviewing and varying food regulatory measures. https://www.foodregulation.gov.au/sites/default/files/2023-09/policy-statement-on-the-public-health-role-of-fsanz.pdf#:~:text=The%20aim%20of%20this%20Policy%20Statement%20is%20to,which%20covers%20matters%20outside%20the%20remit%20of%20FSANZ. Accessed 8 November 2025.

MoH (Ministry of Health) (2020) Eating and Activity Guidelines for New Zealand Adults, Ministry of Health, Wellington. https://www.tewhatuora.govt.nz/assets/For-the-health-sector/Health-sector-guidance/Active-Families/eating-activity-guidelines-new-zealand-adults-updated-2020-oct22.pdf. Accessed 15 April 2026.

NHMRC (2013) Australian Dietary Guidelines, National Health and Medical Research Council, Canberra. https://www.health.gov.au/sites/default/files/australian-dietary-guidelines.pdf. Accessed 12 November 2025. Note: The 2013 Australian Dietary Guidelines are currently under review.

OECD (Organisation for Economic Co-operation and Development) (n.d.) Regulation and innovation, Organisation for Economic Co-operation and Development, Paris. https://www.oecd.org/en/topics/better-regulation-and-innovation.html. Accessed 20 January 2026.

CHAPTER 2: A CRITICAL APPRAISAL OF THE CURRENT APPROACH TAKEN BY FSANZ TO NUTRITION RISK ASSESSMENT

2.1 The conclusions and recommendations of the 2011 review and their implementation by FSANZ

This is not the first time that FSANZ has commissioned a review of its approach to aspects of risk assessment. The earlier review was conducted in 2011 by Angelika Tritscher (FSANZ 2017), who is a well-respected researcher and thought leader in risk assessment, having previously served as Coordinator of Risk Assessment and Management at the World Health Organization (WHO).

The 2011 review found that, in its risk assessments, FSANZ follows a clear and structured process and delivers clarity, consistency and transparency of the risk assessment process and its output. Recommendations in relation to risk assessment in general included:

- developing guidance for a tiered risk assessment approach, including rapid risk assessments and qualitative approaches; and
- the development of guidance on risk-benefit considerations.

In respect of nutrition risk assessment specifically, the 2011 review noted that at FSANZ, like at other authorities, this area had at that time already changed from a focus on classical nutrition aspects such as micronutrient excess or deficiency, to a broader public health approach. In the view of the reviewer, this had been partially driven by discussion about health claims, but also by increasing NCDs incidence.

The reviewer noted that approaches and principles for nutrition risk assessment were, at that time, less well established when compared to other areas of risk assessment. She concluded that more epidemiological and statistical expertise is needed in such assessments.

In summary, FSANZ nutrition risk assessment was viewed as a discipline in transition, comparable to nutrition risk assessment in other jurisdictions at that time, characterized by less international normative guidance, and less practical experience when compared with chemical risk assessment. The reviewer noted that FSANZ was taking a systematic approach, applying international risk analysis principles, and was rapidly advancing.

The response of FSANZ on recommendations made by the 2011 review that are relevant to the scope of the current review are set out in Appendix 1.

2.2 The current approach of FSANZ to nutrition risk assessment

2.2.1 Scope

The scope of FSANZ nutrition risk assessment includes:

- relevant issues in the consideration of applications for authorization of novel ingredients or foods, governed by formal processes and timescales; and
- informing proposals in relation to areas of concern identified internally by FSANZ, where there may be relatively more flexibility in the conduct of nutrition risk assessment.

The current approach of FSANZ to nutrition risk assessment is set out in a transparent manner in published documents (FSANZ 2013; FSANZ 2014; FSANZ 2023), supplemented by an unpublished *FSANZ Guidance Document for Nutrition Risk Assessment (July 2025)* which is a living document and is for internal FSANZ use only. This guidance document was reviewed by the panel and was found to be provisional by its very nature, and describes itself variously as a framework, a training document, a starting point, and as an aid to ensure consistency. The guidance document notes that it can be modified on a case-by-case basis to suit the purpose of each assessment, based on scientific judgement and expertise, and that it will be modified in the light of experience.

The issues which may be subject to nutrition risk assessment are broad in scope, and include a nutrient, a food, a property of food or a substance added to food. Nutrition risk assessment is therefore undertaken for nutrients or substances used for a nutritive purpose, and also for novel foods and special purpose foods. Nutrition risk assessment may also be required in other areas, such as health claims, irradiation of foods and for labelling advisory statements.

The FSANZ approach acknowledges some specific characteristics of nutrition risk assessment:

- it considers risks of deficiency or excess, but also potential health benefits of a nutrient or related substance added to food – in each case using a scientifically robust process;
- it considers effect of a nutrient or substance on the bioavailability of other nutrients; and
- it may assess a whole food or complex mixture by comparing the food to a conventional counterpart food that has a history of safe use as a benchmark.

2.2.2 Process

The FSANZ approach to nutrition risk assessment applies the normative framework for risk assessment that has been developed for and is usually applied to individual

chemical hazards in food rather than to whole foods or dietary patterns. The approach is described in terms of the four sequential steps developed for chemical risk assessment: hazard identification; hazard characterization; exposure assessment; risk characterization. These steps are applied to nutrition risk assessment in the following way:

Hazard identification involves examining the available scientific data on the health effects of the nutrient or food component including epidemiological, clinical or other technical information relating to physiological and biochemical effects and responses. Ideally, the biological mechanism of action is also described.

Hazard characterisation is reasonably well defined for nutrient-related hazards in terms of health-based guidance values, for both deficiency and toxicity.

Exposure assessment follows standard practice. Dietary intake is estimated using dietary modelling that combines food consumption data, such as from national nutrition surveys, with food composition data. This uses internationally accepted methods.

Risk characterization seeks to integrate information from the hazard and exposure assessments to generate a risk estimate. Risk characterization of nutrients may be conducted for different population groups and/or specific at-risk groups.

Assessment of evidence follows a well-trodden path. In assessing the quality of individual studies, including epidemiological studies, FSANZ will typically assess various elements of the study design and method.

Drawing a conclusion about the level of nutritional risk using the available scientific evidence requires scientific judgement and is subject to internal peer review and a public consultation process. For more complex, ambiguous or contentious risk assessments, advice may be sought from external experts in the preparation of the assessment and/or an external peer review may also be commissioned. The stated aim is to ensure that the scientific basis of a risk assessment is transparent, robust and benchmarked against international best practice risk assessment methodologies.

2.2.3 Outputs

The outputs from FSANZ nutrition risk assessment may be structured narrative reviews, rapid systematic reviews or systematic reviews. Judgement is used in selecting the most appropriate type of review, although there are some overriding requirements set by the operating or policy environment of FSANZ. For example, a systematic review is required for the substantiation of health claims. Elements of systematic review are set out in Section 6 of the Australia New Zealand Food Standards Code.

A structured narrative review is a method for synthesizing findings from multiple studies, primarily using text to summarize and explain results. However, aspects of the more formal systematic review process are incorporated into a structured narrative review to produce a scientifically robust and transparent assessment whose conclusions are defensible to all stakeholders including subject matter experts. The structured narrative review is the most commonly used nutrition risk assessment method at FSANZ for applications and proposals. Current practice for nutrition risk assessment is to use an in-depth and structured approach (not a formal systematic review) to produce a critical review of the literature in order to answer risk assessment questions.

The guidance also includes examples of FSANZ applications and proposals with a nutrition assessment component. The list of topics considered through nutrition risk assessment indicates a focus to date on assessment of nutrients and of food components, but less so on foods and dietary patterns.

2.2.4 From risk assessment to risk management

The impact analysis referenced in Chapter 1 noted that, in terms of the regulatory measures used, FSANZ generally defaults to developing food standards. The impact analysis suggests that, in some circumstances, other regulatory measures could be more efficient to create. FSANZ has several different regulatory instruments at its disposal to achieve its objectives. The Act allows FSANZ to develop food regulatory measures which comprise food standards and Codes of Practice. FSANZ can also develop guidelines to assist interpretation of the Food Standards Code on its own initiative or in consultation with the Australian states and territories and other bodies. FSANZ makes limited non-legally binding guidelines available on its website, and some stakeholders have noted this may represent an approach that is currently under-utilized.

The impact analysis referred to in Chapter 1 also notes that designing and implementing a decision-making tool may result in greater uptake of Codes of Practice and guidelines, which can be created and amended in more agile and responsive ways. That document notes that examples of low-risk issues that may be better dealt with in Codes of Practice might relate to placement and promotion of foods in grocery stores. On the other hand, high-risk matters, such as disclosures of allergenic information, would only be appropriate to regulate through food standards.

While the selection of the most appropriate risk management tools is a matter for risk managers and is outside the scope of this review, risk assessment nevertheless has a role to play. Specifically, contingent (or scenario-based) risk assessment advises on the likely effectiveness of a range of policy interventions or other regulatory measures, which for FSANZ may include but would not be limited to the development of a standard. Such an assessment would estimate how residual risk changes under alternative interventions, both alone and in combination. The role of contingent (or

scenario-based) risk assessment in a modern approach to risk governance is explored further in Chapter 6.

2.3 Looking forward: The Roadmap to 2030

As stated above, the work of FSANZ includes both assessment and decision-making in respect of applications to change the Food Standards Code, and the development and implementation of proposals through which FSANZ ensures that the Food Standards Code as a whole remains fit for purpose, supporting strong food safety and public health protections while enabling innovation and efficiency across the food industry.

Proposals are wide-ranging, complex pieces of work requiring detailed review and assessment of scientific evidence, of regulatory options and of stakeholder input from public consultations. While applications to change the Code are generally completed within 12 months, proposals can often span multiple years due to their scope, complexity, evidence requirements, and policy significance.

Given the scale and duration of proposal work, careful prioritisation and forward planning is essential. FSANZ has worked with its partners across the Food Regulation System and with key stakeholders to develop a 2030 Roadmap for its proposals work. The Roadmap (FSANZ 2025) was endorsed by food ministers in November 2025, and is intended to provide a transparent, medium-term planning framework, aligned with the outcomes and priorities of the Food Regulation System Strategic Plan 2025-2028 (Australian Government 2025).

The panel has noted in particular two planned proposals in the Roadmap which may be informed by the proposals in this report for enhancements to nutrition risk assessment that build on current practice in FSANZ.

First, the high level problem statement for the planned review of commercial foods for infants and young children acknowledges that these foods "may not provide for the nutritional needs identified in dietary guidelines, while making many claims about benefits" and that "revising standards can help ensure products support healthy child development, reduce long-term chronic disease risk and build consumer trust". The panel has developed case study 1 to this report to set out some of the considerations that may be relevant to developing a detailed problem formulation statement for this proposal.

Second, the high level problem statement for the planned proposal in relation to nutritive substances and novel foods notes that innovation in these sectors "is outpacing current regulatory categories" and that "clearer, risk proportionate pathways for nutritive substances and novel foods will reduce regulatory burden, support innovation and ensure consumer protection". The panel has developed case study 3 to this report to illustrate a pathway for novel foods that integrates relevant risk assessment and risk governance considerations, applying these to provide a perspective on the approval of A1247 D-Allulose as a novel food.

2.4 Conclusions

The panel has reviewed the documents published by FSANZ on its approach and processes for nutrition risk assessment.

2.4.1 Assessment of current approaches and processes for nutrition risk assessment

The panel found the 2025 Guidance to be a technically strong and internally coherent document that ensures methodological rigor and transparency in evidence review and synthesis. It aligns well with Codex's classical four-step framework for risk assessment (hazard identification, hazard characterization, exposure assessment, and risk characterization) and provides solid operational detail for FSANZ assessors.

The internal guidance on nutrition risk assessment is couched in terms that underline its provisional nature. The panel believes that this review provides an opportunity for FSANZ to be more definitive in its approach and processes for nutrition risk assessment.

The current FSANZ nutrition risk assessment process appears to be particularly driven by the need to process applications for the use of novel ingredients in foods or for the placing of novel foods in the market. This is understandable as there are timescales set in regulations within which such applications are considered. However, FSANZ should not lose its focus on proposals that identify dietary patterns and the foods within them that promote and protect health, as a prospective tool for delivering a national healthy eating strategy. The Roadmap to 2030 therefore provides a useful forward look, having been discussed with stakeholders and endorsed by Food Ministers, that sets out the key proposals that FSANZ intends to deliver in the coming four years. This represents an ambitious and demanding programme of work and, in particular, FSANZ[1] should ensure that the skills and competencies of its nutrition risk assessors continue to facilitate both the assessment of individual applications, and also the scoping and execution of such proposals that ask broader nutrition risk assessment questions.

The panel notes that FSANZ more often uses an in-depth and structured approach (rather than a formal systematic review) to produce a critical review of the literature in order to address risk assessment questions. In the view of the panel, this appears an appropriate approach in the light of resource availability and the urgency of the risk assessment questions that are posed.

[1] Notwithstanding recommendations 6 and 8 of the 2011 review and the steps taken to date by FSANZ to address them.

As with other aspects of risk assessment, drawing a conclusion in nutrition risk assessment requires scientific judgement. The panel believes that it is important therefore to apply safeguards to ensure that any such judgement is sound. The panel noted that FSANZ subjects its scientific judgements in relation to nutrition risk assessment to internal peer review and a public consultation process and, for more complex, ambiguous or contentious risk assessments, this might be supplemented by external expert advice and/or an external peer review. While there is no suggestion that any of the scientific judgements made by FSANZ in its nutrition risk assessments to date have been less than robust, the panel recommends that FSANZ[2] formalizes the range of safeguards it employs to ensure that the scientific judgements that are made as part of nutrition risk assessment are sound and robust, and sets out the criteria used to determine which safeguard(s) should be used in which circumstances.

In terms of the risk management actions that FSANZ takes in response to nutrition risk assessments, there appears to be a default to developing food standards rather than any of the other actions and interventions that FSANZ is empowered to make. FSANZ should make greater use of contingent (or scenario-based) risk assessment which advises on the likely impact and effectiveness of a range of policy interventions or other regulatory measures when used alone and in combination, including but not limited to the development of a standard.

The panel recommends that FSANZ establish a process for oversighting of all assessments to assess the potential cumulative impacts of food innovation and a changing food supply on dietary patterns, and the identification of dietary patterns and the foods within them that promote and protect health. The Evaluation Framework for the Food Regulatory System, currently under development by FSANZ, might provide a useful framework for such an assessment of cumulative impact, which should be: evidence-based; transparent; focused on learning; and undertaken in partnership with stakeholders.

2.4.2 Towards an enhanced approach for nutrition risk assessment

The panel would characterize the current approaches and processes as constituting a robust procedural guide for evidence appraisal within an assessment-oriented paradigm. In essence, it describes how to undertake a nutrition risk assessment.

This provides a sound basis for the assessment of nutrients and novel food ingredients, but may be less well suited to assessments of whole foods or dietary patterns. When undertaking nutrition risk assessment of a whole food or complex mixture, FSANZ does so by comparing the food to the conventional counterpart food that has a history of

[2] Notwithstanding recommendations 11 and 12 of the 2011 review and the steps taken to date by FSANZ to address them.

safe use as the benchmark, rather than *ab initio*. This may be effective at structuring and guiding risk assessments related to nutrient excess and deficiency, but it does not address other nutritional concerns, such as the extent to which introduction of the food may impact dietary patterns, and the consequent impacts on NCDs.

The panel has focused on setting out how current approaches and processes may be enhanced to reflect the decision-led, problem-formulation-driven, and context-integrated approach now recommended under modern risk governance frameworks, such as ISO 31000 and the frameworks developed by IRGC and OECD.

The panel recommends that FSANZ consider opportunities to adopt a more contextualized model of nutrition risk assessment (described in detail in Chapter 6) as part of a broader, responsive system of risk governance. In this model, FSANZ would:

- start with problem formulation that explicitly defines the public health context, the decision to be made, the plausible regulatory options, and the intended outcomes, including a clear articulation of what safe and nutritious food is understood to be, in that context;
- exploit the multiple opportunities available to work with international counterparts in further developing and implementing such an approach;
- frame the hazard not only in isolated nutritional/biochemical terms, but also in its population/public health and dietary context (including consideration of vulnerable sub-populations, cumulative exposure, and displacement effects).

The current FSANZ practice for nutrition risk assessment benchmarks with the Codex framework adopted by jurisdictions internationally. The panel proposes that these procedural stages of Hazard Identification, Hazard Characterization, Exposure Assessment and Risk Characterization would continue to form the scientific core of assessment, within this broader risk governance framework.

The panel argues that an enhanced approach would support further consideration of how potential impacts of dietary patterns may be assessed and integrated into nutrition risk assessment. This would include consideration of how food innovation might change dietary patterns, such as the potential to lead to increases in the consumption of discretionary foods, particularly in the context of the continuing divergence of dietary patterns in Australia and New Zealand from the respective dietary guidelines. This would in turn inform the selection of appropriate risk management and mitigation strategies, to the extent these were consistent with the policy objectives of the Australia and New Zealand Food Regulation System.

As evidenced in Chapter 3, such an enhancement would place FSANZ at the forefront of nutrition risk assessment practice internationally. The panel sets out in Chapter 6 its specific proposals for enhancement of FSANZ nutrition risk assessment, followed by recommendations for a staged approach to implementation of these changes. These proposals are then illustrated by a series of case studies in Part IV of this report.

References for Chapter 2

Australian Government (2025) Strategic Plan 2025-2028, Food Standards Australia New Zealand, Australian Government, Canberra. https://www.foodregulation.gov.au/resources/publications/strategic-plan-2025-2028. Accessed 17 April 2026.

FSANZ (2013) Risk analysis in food regulation, Food Standards Australia New Zealand, Canberra. httsp://www.foodstandards.gov.au/sites/default/files/publications/riskanalysisfoodregulation/Documents/risk-analysis-food-regulation-full-pdf.pdf. Accessed 12 November 2025.

FSANZ (2014) Food consumption data used in dietary exposure assessment, Food Standards Australia New Zealand, Canberra. https://https://www.foodstandards.gov.au/science-data/exposure/foodconsumptiondatau. Accessed 12 November 2025.

FSANZ (2017) External peer review of FSANZ risk assessment practices and procedures, Food Standards Australia New Zealand, Canberra.https://www.foodstandards.gov.au/publications/External-Peer-Review-of-FSANZ-Risk-Assessment-Practices-and-Procedures. Accessed 11 November 2025.

FSANZ (2023) Dietary exposure and intake assessment, Food Standards Australia New Zealand, Canberra.https://www.foodstandards.gov.au/science-data/exposure/foodconsumptiondatau. Accessed 12 November 2025.

FSANZ (2025) Roadmap to 2030, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/about-us/whatwedo/2030-roadmap. Accessed 17 April 2026.

Appendix 1 to Chapter 2

2011 external peer review of FSANZ risk assessment practices and processes:

Consolidated list of recommendations and FSANZ response (as at September 2025)

#	Recommendation	FSANZ Response
Recommendations for improvement in the risk assessment process and documentation		
1	Develop guidance for a tiered risk assessment approach, also for rapid risk assessments; including qualitative approaches and defining specific scenarios requiring a different level of detail in the risk assessment approach. a. Include decision criteria for qualitative rather than quantitative approaches for microbiological risk assessments, and when risk profiling rather than full risk assessments are sufficient. b. Include guidance on when, and to what extent and under what circumstances, existing authoritative risk assessments can be utilized.	This approach is discipline-based. The tiered framework for nutrition risk assessment is guided by relative risk and the availability of evidence and data. As outlined in the internal guidance document, expert judgement by nutrition risk assessors is often required to interpret and apply this framework effectively.
2	For combined (and complex) risk assessments, apply a clear and practical approach for early input from all relevant expertise early in the risk assessment planning process. This could occur early in a consultative process with all available expertise (in particular special advisors e.g. in nutrition); and include 'check-points' throughout the risk assessment development process	All applications received by FSANZ undergo an administrative assessment to determine whether they meet the application requirements and to identify the appropriate assessment procedure. This process involves input from each relevant discipline to ensure an initial comprehensive review.

	to make sure no aspect is overlooked, or decide whether some aspects can be dropped.	
3	Develop a template on report structure and content for combined risk assessment reports, which involve input from several disciplines, including a brief description of content and level of detail for each section, including examples (reference to existing reports).	Our Supporting Documents (summary of evidence assessment) follow a general structure however, each discipline presents its assessment differently, depending on the nature of the evidence available and the specific requirements of the assessment. The internal guidance document outlines the minimum level of detail that must be included in each nutrition risk assessment.
4	Strengthen the evidence base by introducing a systematic and transparent approach on evidence-retrieval (literature searches) and evaluation (grading) of the evidence (including criteria for 'inclusion' and 'exclusion') for all risk assessment areas.	This information is included in each nutrition risk assessment, in line with the internal guidance document, which outlines the minimum level of detail required.
5	Develop guidance on how to balance risks and benefits in risk assessments.	Nutrition risk assessments present both risk and benefit evaluations however, the responsibility for balancing these considerations lies with nutrition risk management. This process often requires expertise in food policy and legislation, as well as professional judgement from experienced nutrition risk managers.
Recommendations related to scientific competence		
6	Consider the need for additional competence in epidemiology and statistics, to be used across all disciplines, for improved data mining (e.g. surveillance data) and improved integration of all data in risk assessment.	FSANZ has staff with general expertise in epidemiology and statistics however, we are not currently resourced to support this as a dedicated position or team.

7	Consider the need to undertake efforts to improve the public image of FSANZ in terms of scientific competence.	FSANZ is widely recognised as a scientifically competent and credible regulatory agency, both within Australia and internationally. It plays a critical role in safeguarding food safety and public health through evidence-based decision-making. Like many regulatory bodies, FSANZ continues to navigate challenges related to resourcing, timeliness, and balancing diverse stakeholder expectations.
8	Continue to ensure a high level of staff training and to provide opportunities to retain scientific staff experienced in risk assessment.	FSANZ continues to prioritise staff training and provides opportunities to retain scientific personnel with expertise in risk assessment. While this is an ongoing focus, it is important to note that FSANZ currently lacks depth in some areas, and succession planning remains a concern.
Recommendation related to transparency and prioritization		
9	There is a need for a clearer/more transparent prioritization process for all work, including those that are decided at the section level.	Applications are generally prioritised based on statutory (reportable) timeframes. Larger public health initiatives, such as the review of infant formula regulations or the introduction of pregnancy warning labels on alcohol, are typically identified as priorities by the broader food system and then referred to FSANZ for consideration. Managing limited resources alongside competing priorities remains a challenge. To support clearer communication and planning, FSANZ is currently developing the *FSANZ 2023 Roadmap*.
10	Establish a simple 'scoping/request' form to require the requester, for example, Australian state and territory	No longer application to process.

	jurisdictions, to clearly formulate the risk assessment need and to provide appropriate information and data. This will also allow FSANZ to estimate resource needs, and consider additional work as well as to prioritize the request.	
Recommendations regarding external peer reviews		
11	Establish a process, including rationale, for when and how external reviews should be undertaken.	All risk assessments and risk management activities undergo internal peer review. External peer review is typically used when in-house experts seek additional collaboration or validation. In such cases, FSANZ Fellows are generally the first point of contact. FSANZ Fellows | Food Standards Australia New Zealand
12	Establish a Declaration of Interest form and evaluation process for reviewers and FSANZ fellows.	Declarations of interest are required from all individuals involved in FSANZ processes, including staff and external reviewers. An independent delegate assesses whether a conflict (real or perceived) exists, and determines the appropriate management approach if necessary.
Recommendation regarding the interaction between risk assessment and risk management		
13	Increase the transparency in the risk management decision-making process.	All assessments and related risk management deliberations considered by the FSANZ Board and Food Ministers are made publicly available for consultation at the preliminary decision stage (known as *CFS – Call for Submissions*), and again in final form once approved (known as *AR – Approval Report*).
14	Consideration may be given to the establishment of a monitoring and evaluation framework for key public	The Australian Total Diet Study is the country's most comprehensive monitoring survey of chemicals, nutrients, and other substances in the diet. It measures

	health issues, subject to priorities and available resources.	the levels of various substances across a wide range of foods typical to the Australian diet. Australian Total Diet Study | Food Standards Australia New Zealand While monitoring and evaluation of broader public health interventions has historically been more ad hoc, a formal evaluation framework is currently under consideration at the broader food regulatory system level (not yet public).
15	Develop guidance on how to express uncertainty in risk assessment and for proper consideration of such uncertainties in the risk management decision-making process.	This information is included in each nutrition risk assessment, in accordance with the internal guidance document, which outlines FSANZ's weight-of-evidence approach.

CHAPTER 3: GLOBAL BEST PRACTICES IN NUTRITION RISK ASSESSMENT

3.1 Introduction

As part of its review, the panel was asked by FSANZ to review global best practices in nutrition risk assessment. Whilst ostensibly providing a benchmarking for nutrition risk assessment processes in FSANZ, the panel sought views from international and other national food risk assessment bodies on key issues that currently challenge nutrition risk assessment, including process-based food categorization and the use of dietary survey data (see also Chapters 4 and 5). These discussions also highlighted some pertinent procedural issues such as post-market monitoring and shifts toward risk governance that address the need for nutrition risk assessment approaches to keep pace with food innovation.

3.2 Methodology

The panel took a staged approach to its review of global best practices in risk assessment:

Desk review. The panel first undertook a desk review of published information on approaches and processes used by other national food regulatory agencies to conduct nutritional risk assessment. The documents that were reviewed are listed in Appendix 1 and key elements of nutritional risk assessment practice that were identified in this initial desk review is provided in Appendix 2.

Semi-structured interviews with key informants. In collaboration with the FSANZ Executive, a purposive sample of agencies with well-developed approaches to nutrition risk assessment in other national jurisdictions or multilateral agencies was identified and invited to be interviewed. Five organizations accepted the invitation and participated in discussions:

- Health Canada,
- UK Department of Health and Social Care (DHSC),
- European Food Safety Authority (EFSA),
- Food Safety Authority of Ireland (FSAI)
- World Health Organization (WHO).

Interview framework. A structured discussion guide (see Appendix 3) was developed, informed by initial discussions between panel members, and key points from the desk review. The guide was shared in advance with identified representatives from each of the five organizations.

There were two main components to the discussion:

(1) probing the rationale, definitions and scope of nutrition risk assessment, particularly in relation to regulatory approvals and public policy; and

(2) the processes followed, including the four stages of hazard identification, hazard characterization, exposure assessment and risk characterization. This latter part of each discussion extended to other forms of food data potentially available for nutrition risk assessment and emerging governance systems.

Further probing addressed issues related to how dietary patterns and the risk of NCDs might be addressed, the emergence of new food categorization approaches that address food processing, and the use of dietary surveys.

Discussion of the above issues was underpinned by an understanding of the interdependence between nutrients, foods and dietary patterns in nutrition risk assessment, which the panel felt was shared among all interview participants.

When discussing foods, a focus on the role of nutrition risk assessment within the authorisation process for novel foods flowed from prior discussions of the panel. Here, the panel noted the problem associated with dietary guidelines in terms of poor adherence, with populations across the globe resisting dietary patterns that would move them more towards dietary guidelines. In practice this would mean consuming less discretionary foods (NHMRC n.d.) and more of recommended food, such as fresh vegetables. The panel also noted that the formulation of effective and focused "shift messaging" is complicated by frequent food product innovation, reformulation and processing such that the composition even of basic foods changes relatively rapidly. Our concern was that regulatory decisions permit more discretionary foods into people's diets and, through the approval of new additives and ingredients, these decisions at the same time increase the attractiveness and availability of a wide range of discretionary foods.

The panel also noted how preliminary analysis of the recent Australian National Nutrition and Physical Activity Survey 2023 (NNPAS) (ABS 2025) demonstrated the penetration of foods high in fat, sugar and salt (HFSS) into otherwise healthy food categories. For example, some foods recognised as discretionary may start off as a cereal grain but product formulation may transform them into foods high in fat, sugar and salt. The panel asked how one might align nutrition risk assessment priorities with the analysis of dietary surveys, which is helping to pinpoint where foods of potential concern are emerging. The panel sought to identify how nutrition risk assessment can be re-designed to identify and then address these issues.

Timing. Discussions took place online using the Microsoft Teams platform between 6 and 21 October 2025, each lasting 60-90 minutes.

Documentation. Notes were taken, shared for verification with interviewees and panel members, and amended as per feedback. These notes served to supplement the desk review and to inform this report.

Thematic analysis. Themes from the discussions were summarized by content analysis, highlighting comments made relating to procedures followed for nutrition risk assessment as they related to nutrients, foods and dietary patterns.

3.3 Themes in nutrition risk assessment

3.3.1 Procedural aspects

Nutrition risk assessment of nutrients, foods and dietary patterns

Reference paradigm. Many national food regulatory agencies (e.g., Health Canada, EFSA, UK Food Standards Agency, FSAI, US FDA) frame risk analysis as assessment–management–communication, with risk assessment comprising four steps as per Environmental Health Criteria 240 (FAO and WHO 2009) or near equivalents. Semi-structured discussions probed how closely this paradigm is followed for nutrients, foods, and dietary patterns.

WHO normative processes. WHO's processes for normative work to develop nutrition guidelines does not directly address nutrition risk assessment for food regulation. Rather, WHO focuses on a well-established guideline development process (WHO 2014), common across nutrition and other WHO normative work, which is particularly notable in its application to the formulation of dietary guidelines. As such, this process is less formalized in terms of quantifying various risk parameters. It looks primarily at evidence relating to desirable and undesirable health effects from food and dietary patterns. The classical chemical risk assessment four-stage methodology is not followed. Nutrition risk assessment flows from an agreed PICO (population/problem; intervention; comparison; outcome) statement (Schardt et al. 2007) to one or more clear and focused problem statements. The assessment then uses GRADE (Grading of Recommendations Assessment, Development, and Evaluation) (Alonso-Coello et al. 2016) to rate certainty in the evidence and so rate the strength of any conclusions. Importantly, GRADE-based frameworks allow integration of contextual factors, and, in the global context, these factors may include access, equity, and human rights.

Nutrients. Approaches taken to nutrition risk assessment of nutrients by national food regulatory agencies closely resemble those taken in chemical risk assessments. For established nutrients used to fortify or supplement foods, modelling of dietary exposures commonly takes a major role in exposure assessment, similar in many ways to risk assessment of food additives. In both cases, modelling of dietary exposures that result from various levels that may be present in or added to different food categories provide estimates of total intakes in different scenarios. This in turn may be compared to health-based guidance values – dietary reference values in the case of nutrients, or acceptable daily intakes in the case of food additives. Where modelling identifies excess intakes of nutrients, this might then be used in regulatory interventions such as setting targets for sodium reduction, or to inform banning of industrial trans fats. Where modelling identified risks of deficiency, interventions may include fortification of staple foods.

EFSA clarified that when assessing bioavailability, suitability or nutrition impacts, it employs methodologies that are complementary to those for chemical risk assessment.

Foods. The panel heard of a greater level of diversity among national food regulatory agencies in the extent to which a nutrition risk assessment approach similar to that for chemical risk assessment is applied to foods. In some cases, nutrition risk assessment has been undertaken for specific foods and results published. For example, the UK Scientific Advisory Committee on Nutrition (SACN) (UK Government n.d.) has published nutrition risk outcomes on plant-based alternatives to cows' milk (SACN and COT 2025).

The term 'novel foods' has general currency amongst regulators and provided a useful entry point for further probing on nutrition risk assessment at the food level. The panel focussed specifically on the role of nutrition risk assessment in the evaluation of novel foods where they require pre-market authorization.

The panel heard several times about the institutional separation between the teams that undertake nutrition risk assessment and those that undertake evaluation of novel foods. This has led to a general focus of evaluation on assessing chemical safety rather than healthfulness. In Health Canada these functions sit in separate bureaux within the Food Directorate, while in the UK these functions sit within separate government departments (DHSC and the Food Standards Agency, respectively), although here there is cross-membership between the independent SACN and the Advisory Committee on Novel Foods and Processes.

Our discussions with EFSA and with FSAI were particularly instructive, as they provided insights into the separation of responsibilities related to the assessment and authorization of novel foods both between different institutions of the European Union, and between the supra-national and national levels. The panel understood that while EFSA will assess the safety of a novel food or novel ingredient, within the constraints of the applicable European Union legislation, any broader concerns such as potential impacts of a novel food on dietary patterns would need to be reflected at a political level, through the discussion and potential vote by Member States on whether or not to grant authorization, or to tighten controls such as changing conditions for use of a novel ingredient, or changing labelling requirements.

EFSA is responsible for the evaluation of novel foods, which is required by European Union legislation. Many novel foods or ingredients are not designed to substitute conventional foods but to complement the existing diet. In such cases, the assessment will include a check on whether anticipated consumption levels of the novel food would lead to any excess intakes, which would be a toxicological evaluation as there is not a currently available methodology to link changes in consumption of individual foods to NCD outcomes. In relatively few cases, a novel food is intended to directly replace another food, for example new sources of insect or plant protein, where a clear intention is to substitute animal or other sources of proteins in diet. In such cases

there is a lack of data needed to model substitution, and it is difficult to foresee any concomitant changes in consumer behaviour. This means that the basis for any assumptions on how authorization of novel foods may change dietary patterns may readily be challenged.

The panel asked colleagues at FSAI whether they would consider the impact of authorizations of novel foods on the total amount of foods HFSS in the diet, or whether the processes for novel food authorization and setting dietary guidelines are completely separate. FSAI colleagues noted that these issues would not be assessed pre-market but that they would maintain a watching brief on possible post-market issues that arise, for example in terms of impacts on total intakes of sodium.

In several of its discussions the panel sought to explore how such post-market monitoring, for example of authorized novel foods, might work. As in Australia and New Zealand, many other high-income countries also conduct periodic national dietary survey programs, analysis of which allows changes in dietary patterns to be tracked. However, the panel heard that such programs are often dependent on funding at the time any new survey is proposed rather than being a rolling program, which results in long and sometimes irregular intervals between successive surveys of typically a decade or more. In the interim, some countries have national monitoring plan for nutrients, the scope of which in some cases is set by national legislation. These provide current information on food composition in relation to one or more specific nutrients and may be combined with data from national dietary survey programs to inform nutrition risk assessment.

In relation to novel foods, the panel heard the view that the consumption of such foods may in some instances be a niche issue for consumers. In such cases, nutrition risk assessment may be informed by dietary surveys in specific groups, e.g. vegetarians, where one might expect to see larger shifts in dietary patterns in response to some novel foods than in the general population.

Dietary patterns. The need to develop regulatory approaches to address the links between dietary patterns and chronic disease has long been recognized by national food regulatory agencies. For example, in its 2008 report *Health Canada's Regulatory Modernization Strategy for Food and Nutrition* (Health Canada 2008), Health Canada acknowledged that its "regulatory toolkit has generally not been used to address components of foods that are associated with increased risk of chronic disease, and the role that food and diet can play in either exacerbating or reducing chronic disease" and resolved to "develop effective strategies for the use of Health Canada's food regulatory levers to address the chronic medical conditions of vulnerable sub-populations and factors which contribute to these conditions."

The national food regulatory agencies described common approaches to developing food-based dietary guidelines, in terms of identifying dietary patterns that might support or undermine good health, based on normative guideline development as advised by WHO. There was also an acknowledgement that evidence from national

dietary surveys in high income countries consistently demonstrate that their populations are in general not adhering to food-based dietary guidelines. The panel consistently heard of challenges to driving greater adherence to food-based dietary guidelines and uptake of other elements of national healthy eating strategies. These related primarily to working across institutional divides, generally between different tiers of government, between those responsible in setting food-based dietary guidelines and those responsible for their integration into, for example, public sector procurement policies, school food policies, or food provision in other institutional settings.

The panel heard limited examples of where the influence of dietary patterns has been evaluated within nutrition risk assessment. One example was that of veganism in relation to maternal health in a report on maternal health from UK SACN. Another was a mandate to EFSA from Nordic countries which sparked a discussion with the European Commission on whether EFSA should investigate the association of foods and dietary patterns with NCD risk. However, on that occasion a revised mandate was not received.

The panel concluded that there are complexities inherent in identifying appropriate risk assessment questions relating to the association of dietary patterns with NCD risk. The panel noted that this might be an area where iteration between risk assessors and risk managers in the problem formulation stage of risk assessment might be particularly helpful.

Recent development in nutrition risk assessment practice

Several of the national food regulatory agencies, in addition to WHO, now use GRADE for assessing the quality of evidence. This is a relatively new development with, for example, SACN using GRADE for the first time in the preparation of its recent report on maternal health.

Practices at WHO are probably most well-developed of any of the agencies. Here, the identification of outcomes will inform application of GRADE, which is outcome-centric. Here, a measure of confidence in strength of evidence which, together with contextual information, will be compiled in a structured way which determines whether a recommendation is made, and whether the recommendation is strong or conditional. The distinction between strong and conditional recommendations reflects overall confidence in the evidence and the extent to which conclusions are likely to be changed by further evidence becoming available. In practical terms, conditional recommendations may require more policy discussion before implementation, or more national or local contextual information. The decision on whether or not to make a recommendation in a WHO guideline remains binary, but a recommendation may be quantitative or qualitative.

The panel also heard that a particular current focus of SACN is the conduct of rapid reviews of evidence in response to the needs of decision-makers, for example its

recent rapid evidence update on processed foods and health (UK Government 2025), compared to full reviews which may typically take two years to complete.

The panel also asked national food regulatory agencies what issues related to risk assessment process they believed were emerging and may complement current processes and approaches. The panel heard of:

- Greater transparency of inclusion criteria and uncertainty analysis in risk assessment;
- an increasing focus on prior thinking and the posing of open questions to risk assessors; and
- an expansion of the reflection of environmental sustainability considerations in nutrition risk assessment, beyond the current focus in some national food-based dietary guidelines, possibly assisted by the development of a common index for comparing nutrition and environmental sustainability risks as had been explored at the 2025 meeting of the International Union of Nutritional Science (IUNS-ICN 2025).

Risk governance

The panel explored the degree to which separation of roles and responsibilities between nutrition risk assessment and risk management were observed in national food regulatory agencies. The panel heard consistently of functional separation between the teams who gather and assess evidence in nutrition risk assessment (where these functions are not undertaken by separately constituted independent scientific advisory committees), and the teams who are risk managers and devise policy recommendations based on that assessment. Analogous separation of roles is also observed by WHO in its guideline development process, between the group that selects and extracts data, and the guideline development group.

This separation was seen by those the panel spoke to as beneficial, providing clarity of purpose for risk assessors, and facilitating a robust and systematic approach to risk assessment, while allowing those formulating policy recommendations to consider other factors to the extent to which they were consistent with safeguards to protect policy formulation from undue influence. Such safeguards variously included:

- avoidance of conflicts of interest among those reviewing evidence, whether government employees or independent scientific advisers; and
- processes to ensure transparency of policy-making processes.

The separation of roles and responsibilities is seen, universally among the national food regulatory agencies the panel spoke to, as a positive aspect of current risk analysis practice. For example, the UK Food Standards Agency's FSA *Chief Scientific Adviser's Science Report on Risk Analysis*, published in 2020 (Food Standards Agency 2020) highlights that institutional changes following the UK's exit from the EU have

brought "a clearer separation between our risk assessment and risk management to ensure the scientific integrity of risk assessment".

The clearest example of institutional separation between risk assessment and risk management was provided by EFSA which, as risk assessor, responds to specific mandates from the European Commission, acting as risk manager, supporting the latter institution's work to implement existing regulatory frameworks. Those mandates would include:

- assessment of novel foods, including consideration of any nutritionally disadvantageous effects that may result from the replacement of conventional foods by novel foods, based on evidence from food business operators;
- safety and bioavailability of novel sources of nutrients;
- scientific evaluation of whether health claims are substantiated, based on evidence from food business operators; and
- advice on implementation of the regulation on food information to consumers, including provisions relating to nutritional declarations on pack.

Regarding the establishment of dietary guidelines in the European Union, this is undertaken at the national level, reflecting the culture and traditions of individual Member States. The role of EFSA on dietary guidelines is limited to advising on the methodology for developing them.

Notwithstanding this orthodoxy, there is a realization that the independence of scientific advisory committees and the functional separation of risk assessment and risk management may make it difficult for risk assessment advice to be translated into action. UK DHSC referred to this question being asked as part of a recent UK parliamentary inquiry, to which the department responded that the recommendations of SACN had not been adopted in only one case – universal fortification of bread-making flour with folic acid – and this had been at the direction of UK Ministers.

It is, of course, valid for Ministers or other legitimate decision-makers to not implement advice from risk assessors where they are outweighed by other justifiable considerations. But this brings into focus the paradox that the current paradigm has created - on one hand risk assessors and decision-makers operate independently of each other yet, on the other, there is a perceived deficit in decision-making when risk assessment advice is not implemented.

3.3.2 Emerging challenges

Process-based food categorization

When the panel asked national regulators to identify emerging issues that might test the approaches currently taken to nutrition risk assessment, it received a range of responses which included: innovation such as the development of cell-based agriculture; and coping with food security issues and global food supply disruption.

However, the most mentioned challenge, and one most likely to be labelled "significant", related to the challenge posed by process-based food categorization to the current paradigm for food and nutrition assessment.

The panel heard differing views during our discussions. Several believed it was still appropriate to ask whether there were any effects of ultra-processed foods on NCD risk beyond that which would be expected based on the current knowledge base using nutrient-based food categorization. Reflecting the salience of this question, several of the national regulators the panel spoke to are working with national health institutes to identify research priorities for better understanding the health impacts of foods categorized as ultra-processed by the NOVA classification (Monteiro 2009). The view of these interlocutors was that we need to look at food as a whole, and address the business model for UPF production and promotion through continued regulatory interventions relating to foods HFSS.

Conversely, the panel heard from others that a growing body of epidemiological evidence now consistently shows associations between consumption of foods classified as ultra-processed (NOVA category 4) and various adverse health outcomes. Their view, importantly, was that the potential misclassification bias associated with the NOVA system is unlikely to fully account for the observed relationship, as such biases would generally be expected to attenuate rather than exaggerate any true associations. This led to a view on their part that a link between ultra-processed foods and NCDs had been sufficiently demonstrated and that the critical current debate related to the biological and behavioral mechanisms underlying these associations. These interlocutors suggested that, in the meantime, regulatory interventions should now focus on ultra-processed foods as it would be unethical to wait for any novel mechanisms to be identified when the association between dietary patterns and NCD risk is, in their view, very clear at the population level.

The panel, while noting the current debate, focused on how issues related to process-based food categorization might pose challenges to nutrition risk assessment. This was a particular focus of the panel's discussion with WHO.

WHO colleagues noted that nutrient-based and process-based approaches to food categorization are not mutually exclusive as many ultra-processed foods are foods HFSS, and vice versa. Accordingly, there is a need to look at both approaches when framing dietary recommendations. WHO colleagues noted that current criteria for ultra-processed foods also include consideration of non-nutritive food additives and suggested that a solely nutrient-based approach would overlook evidence, for example on the effects of some food additives on the gut microbiome.

The panel noted that it would also be possible, for example, to have a sugar-sweetened breakfast cereal that fell short of the thresholds for foods HFSS, but once non-nutritive ingredients were added to increase organoleptic appeal, this food would then be likely to be classified as an ultra-processed food. In terms of the impact on the overall diet, this might then lead to greater consumption of this more attractive

product which might in turn lead to individuals in some sections of the population exceeding dietary guidelines for sugars, with the only dietary change being increased consumption of breakfast cereal products not themselves classed as foods HFSS.

Looking forward, the panel heard from WHO about their work to develop a guideline on the consumption of ultra-processed foods. Their call for experts had closed (WHO 2025) and, at the time of our discussion with them, an announcement on the membership of the resultant panel was imminent.

That announcement was subsequently made, and WHO updated the 48th session of the Codex Alimentarius Commission in November 2025 on its plans (FAO and WHO 2025). This confirmed that, at that time, WHO was planning to develop guidance in two parts:

- an operational definition of UPF, which would be key to providing actionable advice and might be used to inform distinctions drawn between food products when implementing regulatory interventions targeted at UPF – this would be particularly valuable in countries which have not developed an approach to nutrient profiling; and
- a WHO guideline on consumption of ultra-processed foods, which might be qualitative (e.g. to limit consumption) or quantitative (e.g. UPF as a proportion of the overall diet)

The panel noted that the WHO work on UPF would be expected to take around two years and so any WHO guideline would not have been developed by the time the panel submitted its report to FSANZ.

Integrating National Dietary Survey Data with Other Sources

National dietary surveys provide the basis for understanding overall dietary patterns, the nutritional health of the population, the broader food environment, and food security issues. For example, in the UK, its National Diet and Nutrition Surveys (NDNS) are used to identify populations at risk and nutrients of concern, which then inform topics for prioritization of reviews undertaken by SACN.

Notwithstanding the utility of national dietary surveys, they are costly and relatively infrequent, even in high income countries, and the quality of the data they provide varies with the methodology used.

The panel noted that food innovation is a 'moving train' with rapid emergence of new foods and ingredients. The panel asked how then one should monitor the emergence of new foods and their impacts on food consumption patterns. Responses focused on the challenge of maintaining up-to-date food composition data.

EFSA described its work to improve methodology for collecting food composition data at the national level in Europe. This focuses on the food product that is consumed, rather than the category of that food, to help account for issues such as novel meat

products with added fibre, which would not otherwise be captured. The panel noted that without an approach that collects granular, product-specific data, it will be difficult to assess the nutrient content of the diet as it changes and link it to NCD incidence. However, it is currently an open question as to whether food composition tables will ever be detailed and agile enough to keep up with the pace of innovation in foods and food ingredients, in the absence of ongoing collaboration with food manufacturers directly about the contents of their products on the market. It would not be sufficient to rely, in the case of novel foods and ingredients, on data submitted by the manufacturer to support authorization as these would tend to list any food category in which the product might be used, together with maximum use levels, and so overestimate actual consumption. An alternative to ongoing collaboration with food manufacturers would be to purchase granular data on food composition, which is available commercially but at a price.

In our discussions with Health Canada, the panel noted that their approach combines pre-market risk assessment with post-market surveillance. Even here, data availability may be a problem. There may, however, be opportunities to leverage new technologies for nutrition and safety risk assessment, such as the use of AI or digital tools to collect information which is currently lacking.

FSAI colleagues noted they seek and use food composition data from food manufacturers from time to time, and their national reformulation task force undertakes market research and has a repository of information which could be used to a greater extent for nutrition risk assessment, although its coverage is partial as it focuses on changes in the market in specific food categories and related to specific nutrients.

Risk-benefit assessment of foods

While most national regulators expressed an interest in risk-benefit assessment of foods, examples of this practice were limited. This may be related to institutional separation between teams assessing nutritional benefits and those assessing toxicological or biological risks.

There were, however, examples of working across these divides, for example the current reassessment by Health Canada of mercury which, in term of the dietary advice that might result, will take into account the nutritional benefits of food categories in which mercury may be found, and highlight foods within those categories that typically have lower levels of mercury contamination. The panel also noted the recent example from the UK of collaboration between independent scientific advisory committees on nutrition and on toxicity in the production of their recently published report on plant-based alternatives to cows' milk and their previous joint report on fish consumption (SACN 2004).

3.4 Conclusions

3.4.1 A comparison of current FSANZ approaches to global best practices

The panel would see the other national food regulatory organizations it interviewed as FSANZ's peers. The panel concludes that the current approaches of FSANZ to nutrition risk assessment are largely comparable with and equivalent to the approaches used by those other organizations in terms of their development, sophistication, agility, and openness to consider developments in scientific knowledge relating to food and nutrition.

Particular elements of global best practices already included by FSANZ in its approach and process for nutrition risk assessment include:

- In common with the WHO normative approach to guideline development, FSANZ uses the PICO (population/problem, intervention, comparison, outcome)/PICOTS (population, intervention, comparator, outcome, time, setting) approach to define inclusion and exclusion criteria when screening studies for inclusion in the risk assessment, and the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach to assess the certainty of evidence in a structured way to assign a rating of high, moderate, low, or very low certainty to the evidence. SACN in the UK has also used GRADE but only more recently, in preparation of its recent report on aspects of the diet and maternal health.
- FSANZ has a documented approach that delivers flexibility in the types of review conducted, with an increasing reliance on structured narrative review as it is often appropriate, risk-proportionate, and resource effective. This has some similarities to the current focus of SACN in the UK on the conduct of rapid reviews of evidence.
- FSANZ demonstrates a clear understanding that nutrition risk assessment questions need to be clearly defined and involve an iterative process between the project manager for risk assessment and risk assessors prior to commencing the assessment.

Opportunities to learn from best practices used by other national food regulatory organizations include:

- SACN in the UK has recently expanded its application of nutrition risk assessment to articulate nutrition risk outcomes in relation to consumption of specific food types, in its recent report on plant-based alternatives to cows' milk.
- FSAI maintains a watching brief on post-market issues; some countries have national monitoring plans for nutrients in the intervals between successive national nutrition surveys; EFSA is developing food composition methodology to collect more granular, produce-specific data. Each of these approaches may

provide elements which could be integrated into a process of post-market surveillance to complement pre-market risk assessment. Health Canada appears most advanced in efforts towards this goal.

In the light of the above considerations, the panel supports the contention in FSANZ's 2025 Guidance document that "FSANZ uses international best practices in its risk assessment to develop world-leading food standards."

The panel would characterize all the national food regulatory organizations as having robust procedures for evidence appraisal within an assessment-oriented paradigm. As the panel notes in Chapter 2, this is a characteristic shared with FSANZ. Like FSANZ, several of the other national food regulatory organizations have been incrementally developing their approaches to nutrition risk assessment over the past decade or two, having long recognized the need to address components of foods that are associated with increased risk of chronic disease, and the role that food and diet can play in either exacerbating or reducing chronic disease. This observation raises the question of whether the enhancements to current processes recommended by the panel in this report – which would deliver the decision-led, problem-formulation-driven, and context-integrated approach that the panel advocates – would in the real-world be best developed by FSANZ alone, or collaboratively with other, like-minded national food regulatory organizations.

3.4.2 Do current approaches to nutrition risk assessment follow the four-stage normative process?

The panel tested the extent to which nutrition risk assessment follows the four-stage normative process used universally for chemical risk assessment. The panel heard evidence of this being the case in, for example, the assessment of safety of ingredients of infant formula, but noted that even in the relatively straightforward case of nutrition risk assessment of nutrients there was some divergence in international practice from the normative process for chemical risk assessment. As the subject of nutrition risk assessment increased in complexity, from nutrients to foods to dietary patterns, and the questions posed to risk assessors also became more nuanced, there was a widening divergence between chemical risk assessment approaches and the nutrition risk assessment approaches used in practice. Elements of the process for nutrition risk assessment commonly described to us included:

- identification of potential hazards;
- setting the scope for the risk assessment, considering multiple hazards and multiple health outcomes, both positive and negative;
- review, summary and quality assessment of relevant literature;
- consideration of dietary consumption data;
- commissioning of any necessary modelling or scenario-based work;
- making a judgement on whether a particular nutrient, food and/or food component, or dietary pattern is contributing to any observed effects in the outcome, based on the quality and quantity of the available evidence; and

- drawing conclusions and making recommendations.

3.4.3 Emerging challenges

The panel noted that the emergence of frameworks for process-based food categorization is likely to be a significant driver for food policy in the near future. The challenges that this would pose to the current risk assessment paradigm are fundamental. Data availability is seen as a major issue, as all national dietary surveys and tools look at levels of nutrients rather than probing for levels of processing, and there is no food label database that can consistently identify ultra-processed foods, and no database to determine which food products are the result of which processes. These issues are explored further in Chapter 4.

The panel noted the current limits to *a priori* consideration of the potential impacts of novel foods and ingredients on dietary patterns. The panel envisages a continuous process for novel foods and ingredients that includes both pre-market risk assessment focusing on toxicological assessment during the approvals process, with post-market monitoring and surveillance of changes to food consumption and dietary patterns.

One tool currently available to FSANZ for the tracking of longitudinal trends in consumer behavior is its annual tracker survey. Improved post-market monitoring and surveillance would require more targeted, frequent and ongoing monitoring of the food supply to provide updated information on food composition and processing at the level of individual products, possibly in collaboration with food manufacturers. This would help support future assessment of the impacts of food innovation on dietary patterns, and any future process-based food categorization.

3.4.4 The potential for FSANZ to convene an international community of practice

The participants in the semi-structured discussions uniformly demonstrated a high level of engagement and expertise, a commitment to collaboration, and a desire to learn from any recommendations the panel may make. This provides an opportunity for FSANZ to convene an informal group, such as a community of practice, as part of its response to this report, to facilitate further collaboration and shared learning. A plurilateral consideration of options for the development and enhancement of nutrition risk assessment approaches may also mitigate some of the risk of otherwise unilaterally pursuing a divergent nutrition risk assessment approach that may disrupt existing trade patterns. A community of practice, once established, may provide an opportunity to pilot activity in collaboration with other influential, respected and like-minded national food regulators.

References for Chapter 3

ABS (Australian Bureau of Statistics) (2025) National Nutrition and Dietary Activity Survey, Australian Bureau of Statistics, Canberra.

https://www.abs.gov.au/statistics/health/food-and-nutrition/national-nutrition-and-physical-activity-survey/latest-release. Accessed 28 October 2025.

Alonso-Coello P, Schuenemann HJ, Moberg J, Brignardello-Petersen R, Akl E A, Davoli M, Treweek S, Mustafa RA, Rada G, Rosenbaum S, Morelli A, Guyatt GH, Oxman AD and the GRADE Working Group (2016) GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction, *BMJ* ,353:i2016, doi:10.1136/bmj.i2016.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization) (2009) Environmental Health Criteria 240: Principles and methods for the risk assessment of chemicals in food, Food and Agriculture Organization of the United Nations and World Health Organization. https://www.who.int/publications/i/item/9789241572408. Accessed 31 October 2025.

FAO and WHO (2025) WHO guidance on "ultra-processed" foods (UPF) in Matters arising from FAO and WHO, CX/CAC 25/48/15, Food and Agriculture Organization of the United Nations and World Health Organization. fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-48%252FWorking%2Bdocuments%252Fcac48_15e.pdf. Accessed 21 January 2026.

Food Standards Agency (2020) Chief Scientific Adviser's Science Report: Risk Analysis, Food Standards Agency, London. https://www.food.gov.uk/sites/default/files/media/document/csa-report-risk-analysis.pdf. Accessed 28 October 2025.

Health Canada (2008) Regulatory Modernization for Food and Nutrition, Government of Canada, Ottawa. https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/acts-regulations/regulatory-modernization.html. Accessed 28 October 2025.

IUNS-ICN (The International Union of Nutritional Sciences - International Congress of Nutrition) (2025) International Congress of Nutrition Program Book: Sustainable Food for Global Health, The International Union of Nutritional Sciences - International Congress of Nutrition, Paris. https://www.icn2025.org/storage/uploads/529f6ef5-0ce9-440a-9fce-8326aa69a55c/ICN25_ProgrammeFinal---27.10.25.pdf. Accessed 31 October 2025.

Monteiro CA (2009) Nutrition and health. The issue is not food, nor nutrients, so much as processing, *Public Health Nutrition*, 12(5):729-31, doi:10.1017/S1368980009005291.

NHMRC (n.d.) Discretionary food and drink choices, National Health and Medical Research Council, Canberra. https://www.eatforhealth.gov.au/food-essentials/discretionary-food-and-drink-choices. Accessed 28 October 2025.

SACN and COT (Scientific Advisory Committee on Nutrition and Committee on Toxicity) (2025) Assessing the health-based benefits and risks of consuming plant-based drinks. Scientific Advisory Committee on Nutrition and Committee on Toxicity, London. https://assets.publishing.service.gov.uk/media/68765a24cfc3756455bb6a61/plant-based-drinks-health-benefits-and-risks_main-report.pdf. Accessed 28 October 2025.

SACN (2004) Advice on fish consumption: benefits and risks, Science Advisory Committee on Nutrition, London. https://cot.food.gov.uk/sites/default/files/cot/fishreport200401.pdf. Accessed 29 October 2025.

Schardt C, Adams MB, Owens T, Keitz S and Fontelo P (2007) Utilization of the PICO framework to improve searching PubMed for clinical questions, *BMC Medical Informatics and Decision Making*, 7:16,. doi:10.1186/1472-6947-7-1.

WHO (2014) WHO Handbook for Guideline Development, 2nd edition, World Health Organisation, Geneva. https://www.who.int/publications/i/item/9789241548960. Accessed 28 October 2025.

WHO (2025) Call for experts to develop a WHO guideline on consumption of ultra-processed foods, World Health Organisation, Geneva. https://www.who.int/news-room/articles-detail/call-for-experts-to-develop-a-who-guideline-on-consumption-of-ultra-processed-foods. Accessed 29 October 2025.

UK Government (n.d.) Scientific Advisory Committee on Nutrition (SACN), UK Government, London. https://www.gov.uk/government/groups/scientific-advisory-committee-on-nutritionwww.gov.uk/government/groups/scientific-advisory-committee-on-nutrition. Accessed 28 October 2025.

UK Government (2025) Processed foods and health: SACN's rapid evidence update summary, UK Government, London. https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update/processed-foods-and-health-sacns-rapid-evidence-update-summary. Accessed 28 October 2025.

Appendix 1 to Chapter 3

DOCUMENTS SUBJECTED TO DESK REVIEW

From its search for published sources on information on risk assessment undertaken by other national regulatory bodies, FSANZ identified the following which were the subject of the initial desk review by the panel.

Health Canada: The Food and Nutrition Directorate includes the Bureau of Nutritional Sciences that works to address nutritional risks associated with the food supply.

ARCHIVED - Health Canada's Regulatory Modernization Strategy for Food and Nutrition - Canada.ca See Goal three: Modernizing the Regulatory Toolkit to Address "Food Contributors" to Chronic Disease

A primer on Scientific Risk Assessment at Health Canada (Saner, 2010)

Weight of Evidence: General Principles and Current Applications at Health Canada 2018 Annex 2. Working Level Interpretation(s)/application(s) of Weight of Evidence p. 16 relevant to Nutrition Risk Assessment e.g. Novel foods, nutrition labelling and claims

Guidance for Evaluating Human Health Effects in Impact Assessment: Human Health Risk Assessment (2010)

European Food Safety Authority (EFSA): Similarly, EFSA documents relate to general risk assessment:

Four Steps of Risk assessment

Methodologies | EFSA

Nutrition applications: regulations and guidance | EFSA

Guidance and other assessment methodology documents | EFSA

Guidance on risk–benefit assessment of foods

Dealing with Evidence | EFSA

RiskBenefit4EU – Partnering to strengthen Risk-Benefit Assessment within the EU using a holistic approach | EFSA

Open EFSA is the single public interface for all information related to EFSA's scientific work. It includes information on risk assessment process from receipt of the dossier

to adoption of the opinion: status of assessments, dossier and studies (non-confidential versions), info on experts, and more.

EFSA conference 2018 – Science, Food, Society | EFSA

Food Standards Agency UK

The Risk Analysis Process | Food Standards Agency

Risk Analysis - Chief Scientific Adviser's Report

US Food and Drug Administration

Risk analysis at FDA: Food Safety A science-based approach

Initiation and Conduct of All "Major" Risk Assessments within a Risk Analysis Framework

FSANZ

FSANZ Guidance Document for Nutrition Risk Assessment [Internal Use Only] July 2025

Appendix 2 to Chapter 3

KEY ELEMENTS OF NRA IDENTIFIED IN THE INITIAL DESK REVIEW OF WEBSITES OF NATIONAL REGULATORY BODIES.

Feature	FSANZ	USFDA	EFSA	UK	Canada
Framework	Hazard identification Hazard characterization Exposure assessment Risk categorization	Hazard identification Hazard characterization Exposure assessment Risk categorization	Hazard identification Hazard characterization Exposure assessment Risk categorization	Hazard identification Severity of risk Likelihood of illness Risk characterization (aligned with Codex; historically EFSA)	Problem formulation Exposure assessment Toxicity assessment Risk characterization Uncertainty and sensitivity assessment Extent of effects and risk determination
Methodologies	Key questions	Process examining	PROMETHEUS	(Scientific advisory committees)	Totality of evidence

Feature	FSANZ	USFDA	EFSA	UK	Canada
	Critical analysis and review Dietary exposure Types of NRA: systematic reviews Structured narrative review Rapid review	likelihoods of adverse reaction Based on models (Cycle of inputs & outputs) Review/refine scope Collect data, information Develop, validate model Review results Draft documents	Systematic review of evidence plus other sources Specific requirements for several areas relevant to nutrition assessment *	Risk assessors determine tools and approaches Best available evidence, transparent, unbiased. 100 scientific experts: evidence division, statisticians, economists, social scientists. Multidimensional representation of risk Uncertainty and variability factors Published evidence Temporary risk management – where there is insufficient scientific evidence	Weighing of evidence (refs EFSA, USEPA, ECHA, WHO, Codex)
Other features	Ministerial policy guidelines Time vs quality /Type of review Risk consideration	Major risk assessments identified and selected	'new micronutrient sources'. https://doi.org/10.2903/j.efsa.2024.8946	Additional factors include consumer interests (environment, food security) and habits (acceptability); economic impact; technical and feasibility issues	Food systems referenced, and alignment of food safety with nutrition efforts.

Feature	FSANZ	USFDA	EFSA	UK	Canada
			health claims https://doi.org/10.2903/j.efsa.2017.4680 special foods https://doi.org/10.2903/j.efsa.2021.6544 risk benefit of foods https://doi.org/10.2903/j.efsa.2024.8875 https://doi:10.2903/sp.efsa.2019.EN-1768	(capacity/science/enforcements etc) Registers of Risk assessment issues, regulated products	

Appendix 3 to Chapter 3

STRUCTURED GUIDE FOR DISCUSSIONS WITH AGENCIES IN OTHER NATIONAL JURISDICTIONS AND MULTILATERAL BODIES

Rationale, definitions and scope for nutrition risk assessment

In which of the following instances would your organization undertake an assessment of nutrition-related aspects, either for the purposes of regulatory approval of a food product, or to inform the development of public policy:

- Composition and labelling of food and drink for sport performance
- Regulatory approval of vitamin or mineral formulations for use in infant formula
- Regulatory approval of novel nutritive ingredients in other food products whose composition is protected by law
- Regulatory approval of novel foods, novel processes, or other regulated products
- Sufficiency of nutrient intakes
- Association of dietary patterns with non-communicable disease risk

For any where you do not undertake an assessment, would this be a responsibility of a different part of government? If so, which?

For any where you do undertake an assessment, how would you describe the purpose of the assessment:

- To inform regulatory approval or post-market control of a food product?
- To inform the development of public policy?
- Other (please specify)?

What number of such assessments did you undertake in 2024 (or in any other past year, if that gives a more representative picture)?

FSANZ would call the process of assessment in these circumstances "nutrition risk assessment". What would you call it? Is there any published definition or scope statement for your preferred terminology?

Process of nutrition risk assessment

Would you consider that [your preferred terminology] follows a structured approach? Is a description of this process publicly available?

If yes, does this approach follow the four stages of risk assessment – hazard identification, hazard characterization, exposure assessment, and risk characterization?

If no, is a set process followed for each assessment, or is the most appropriate process selected for each assessment on its own merits? How would you briefly describe the approach followed?

Other

Are there any worked examples of [your preferred terminology] or case studies that you have published which might be useful for us to consider as part of the FSANZ review of nutrition risk assessment?

Are there any emerging issues related to [your preferred terminology] that you feel might test the approaches that regulatory bodies and their advisers take to nutrition-focused assessment?

PART II: KEY CHALLENGES AND OPPORTUNITIES FOR NUTRITION RISK ASSESSMENT

CHAPTER 4: FOOD CATEGORIZATION

4.1 Introduction

The panel considered food categorization to be an emerging issue that might test approaches to nutrition risk assessment. A 'deep dive' review was undertaken to clarify the issue and highlight the challenges it poses for nutrition risk analysis.

The FSANZ strategic plan (Australian Government 2025) targets a healthy food supply, that is, one that aligns with the dietary guidelines of Australia (ADG) and New Zealand. The goal of dietary guidelines is to advise on the types and amounts of foods that create healthy dietary patterns that meet requirements for nutrients and protect against NCDs.

Both the ADG and FSANZ approaches to nutrition refer to nutrient based categories of food, reflecting key components (carbohydrates, proteins, fats, essential vitamins and minerals). Guidance is based on consumption of these core food groups, while limiting discretionary foods which are of poor nutritional value and high in sugar, sodium and saturated fat. While discretionary foods are defined in terms of nutrient excess, they are poorly identified as foods, and their relative consumption reflects current unhealthy dietary habits (Tapsell et al. 2016). As these nutrient excesses (saturated fat, sugar, sodium) have also been attributed to food processing, new food categorization systems have evolved in the literature relating to degrees of 'processing', such as the NOVA system (Monteiro et al. 2019).

The key questions are what are the limitations of nutrient-based vs process-based food categorizations for food regulators and are they mutually exclusive?

4.2 Methodology

With a focus on most recent activity, multiple sources of information were identified and synthesized to establish a broad perspective relevant to nutrition risk assessment in Australia. The panel commissioned FSANZ to retrieve information relating to diet quality and processed foods, including previous publications relating to UPF from the FSANZ Chief Public Health Nutrition Advisor. Details on food categories listed in the Food Standards Code were retrieved from the FSANZ website. The international context was considered in project interviews with food regulators and reviews of related websites and targeted publication. This included reports on recent workshops on Ultra-Processed Foods and the newly released Lancet series on UPF. Key issues and gaps raised by global experts and professional groups were identified. Relevant outcomes from the November 2025 Codex (CAC48) meeting were included. To assist in translation, insights from further engagement with FSANZ teams were incorporated.

4.3 Definitions of Nutrient-based and Processed-based Food Categories

4.3.1 Nutrient-based Frameworks

Traditional nutrient-focused approaches have dominated nutritional science and public health for decades, emphasizing specific nutrients such as sodium, saturated fats, and added sugars as risk factors for diet-related diseases. Food-based dietary guidelines have been the basis of public health recommendations for over half a century, typically focusing on food sources of individual nutrients and their quantities, such as vegetables, fruit, wholegrains, protein rich foods (meat, fish, eggs, nuts, milk, cheese) and culinary oils. With guidance on added sugar, salt, and fats, these tend to be unprocessed or minimally processed. Tools like the Nutri-Score (2020) (Eurofins 2024) evaluate foods based on nutritional content, and epidemiological studies have established strong evidence linking dietary factors such as high amounts of sugars, salt, and saturated fats with chronic diseases. The scientific concordance for these nutritional factors supported food-based dietary guidelines and front-of-pack nutritional labels. However, this nutrient-centric perspective has limitations. Focusing on nutrients alone overlooks synergistic effects between foods and neglects how food structure and processing affect nutrient bioavailability and metabolic, behavioral and satiety responses. A nutrient analysis may not fully capture the health effects of high levels of processing, as ingredients-based approaches fail to account for possible processing effects.

4.3.2 Processed-based Frameworks

This approach, exemplified by the NOVA classification, represents a paradigm shift from nutrient reductionism to considering the nature, extent, and purpose of industrial food processing. Six systems of processing-based food classification have been identified: NOVA, EPIC/AIRC, IFPRI, UNC and the Siga score (Bernstein et al. 2026; Medin et al. 2025). One systematic review suggested that the Siga system may be a better alternative as it distinguishes between additive types and included quantitative measures of nutritional quality (Medin et al. 2025).

The NOVA framework proposes that industrial food processing is the key to explaining the relationship between food and health, with the degree of processing potentially more significant than nutrient content in determining health outcomes. The processing approach considers physical, biological, and chemical processes used after foods are separated from nature, including how these processes alter food structure, add industrial substances, and create novel compounds. This perspective captures aspects beyond nutrient content, such as processing techniques, additives, and food matrix modifications. One fundamental advantage is that processing-based classification provides a more comprehensive understanding of how modern industrial food production affects health outcomes. It recognizes that foods with the same nutrients delivered in different food matrices can have divergent health effects, explaining why

studies adjusting for nutritional quality still find residual processing-related risks. For these reasons, it is necessary to keep a watching brief on the science behind the processed food narrative.

Table 4.1 Comparative Benefits and Limitations of Nutrient and Processed Based Approaches to Food Categorization

Nutrient (ingredients) based approach	Processed based approach
Established evidence base with clear nutrient targets	Captures health effects not explained by nutritional composition alone
Ability to address specific nutrient-related health issues	Considers food matrix alterations and their metabolic consequences
Quantifiable metrics for food reformulation	Addresses additives and contaminants not reflected in standard nutrient profiles
Focus on ensuring nutrient adequacy	Accounts for eating rate, satiety, and consumption patterns
Fails to capture ultra processing effects on health	Heterogeneity within food categories
Overlooks how food structure affects nutrient availability	Relies on subjective classification
	Potentially misclassifies 'healthy and 'unhealthy' foods

The panel considered whether this says something about the nature of the ADGs that inherently support the consumption of commodity foods (fruits, vegetables) in deference to processed foods with higher amounts of sugar, salt and fat. Could the emergence of processed food categories take the guidelines further? Given the

increasing problems of obesity and metabolic disorders, could it be that nutrient-focused categories best identify foods to recommend, but processed-based categories better identify foods to limit?

4.4 International Perspectives

While nutrient-based food categorizations have been the norm in assessing diet quality, the limitations of the UPF categorization are well recognised by international organisations and debated within the scientific literature. Issues related to UPFs were considered in the interviews on nutritional risk assessment with international comparators (see Chapter 3) and are briefly discussed here with reference to relevant literature.

Canada: As with all the project interviewees, Health Canada informants noted that the UPF categorization presents a significant challenge to the paradigm that has been used for food and nutrition assessment. In June 2024 it co-hosted a Best Brains Exchange *Unpacking Ultra-Processed Foods- Identifying Research Priorities* (CIHR 2024) aimed at identifying knowledge gaps and research priorities on the impact of UPF on health. Information from this site noted that almost half the energy consumed by Canadians was from processed food, that the NOVA classification was the most used in research, and that there was consistent epidemiological evidence of high UPF consumption and increased risk of adverse health outcomes with non-communicable diseases. The certainty of this evidence, however, was rated low and more research was needed.

This was consistent with research showing that at a dietary pattern /population level, disease risk associations appear consistent between NOVA and nutrient based diet quality indices, but there is poor concordance at the individual food level and when it comes to identifying foods to limit (Mackerras 2019a).

European Union: The situation with EFSA is different as one of the main reference points for nutrition assessment – Dietary Guidelines - is developed at the Member State level reflecting their diverse cultures and traditions. EFSA supports the implementation of regulation by providing guidance on quality scientific review of evidence (EFSA n.d.) and guidance on specific nutrition related processes (for example Health Claims (EFSA NDA Panel 2017); special foods (EFSA NDA Panel 2021); risk benefit of foods (More et al. 2024). While the approach to guidance maintains a largely nutrient-based food categorization system, the focus of evaluation is more on whole foods.

It appears unlikely EFSA will change its methodology before convincing data shows whether level of processing, over and above nutrient composition, has any effect on health. This remains the case in Member States, such as Ireland, where UPF are part of a watching brief. In Ireland, as in Australia, a nutrient-based approach to food categorization is applied in dietary guidelines (supported by dietary modelling). Approval of novel foods relies on EFSA safety assessments which are largely chemically

based and do not consider the impact on total diet. Nevertheless, the applications of nutrient profiling within the regulatory system may need to be reconsidered.

United Kingdom: In the UK there is a distinction in responsibilities for chemical and biological food safety (in the FSA) and nutrition (in SACN/DHSC). The FSA considers the chemical and microbiological safety of foods, which traditionally uses a nutrient-based (or chemical) approach. While the UPF issue may be one area where the two branches might work together, the view is that more work needs to be undertaken with definitions. For example, it is unclear whether the categorization is just about additives in food.

That said, the panel heard that there are areas where SACN and FSA have demonstrated they can work together, for example in the report on plant-based drinks. (SACN and COT 2025). Another is the area on sweeteners. While the SACN statement has blurred lines of responsibility between DHSC and FSA, it addresses lower dose chronic effects (SACN 2025a).

This adds to considerations beyond standard toxicology and may pave the way in which long term nutrition considerations can be integrated using both process- and nutrient-based approaches in nutrition assessment. In this case, identifying key food groups for consideration might lead to greater specificity in dealing with problem areas in unhealthy dietary patterns. Indeed, in the SACN rapid review of processed food (SACN 2025b), while the quality of the evidence for links with chronic disease remained a problem (due to dependence on observational studies), the food groups which dietary guidance advises to limit were ever present in the evidence on processed food.

USA: Authoritative webpage searching found a recent brief from the (US) National Centre for Health Statistics that clearly shows an interest in the UPF food category. In this report, during August 2021–August 2023, most foods consumed were referred to as 'ultra-processed'. The mean percentage of total calories consumed from these foods among those ages 1 year and older was 55.0%. Cereal based foods such as sandwiches (including burgers), sweet bakery products, and savory snacks, as well as sweetened beverages were four of the top five sources of calories from ultra-processed foods among youth and adults. (CDC 2025). Similar to the position in Canada, a USDA-NIFA funded workshop (#2022-07671) was held in 2023 to develop a research roadmap to identify research priorities on processed food intake and the risk of obesity and cardiometabolic diseases in the US population. Seven key research questions emerged including those related to objective methods for categorizing UPFs, considering food processing and formulation, and improvements in exposure assessment of UPF intakes (O'Connor et al. 2023).

One of the outcomes of this work was a set of nine guiding principles for scientists developing and applying classifications based on food formulation and processing. Perhaps the most pertinent to food regulation were the last two principles which referred to considerations for using a categorization system: the context in which the

system was validated and the probative value of the research question (Bernstein et al. 2026). In this case, the food classification system applied would need to match with the questions raised in the problem formulation.

Australia: The concept of UPF can also be found at the forefront of food research in Australia. In 2024, a research roadmap for priorities on UPFs in the context of the Australian food system was developed by a group of researchers under an NHMRC grant (APP2034008) (Machado et al. 2025). This qualitative review of expert opinions (n=27) reported on priorities for science (including measurement tools), for policies and practice (including novel regulatory mechanisms and monitoring systems) and political commitment (including government structures and food dominance).

The review noted the many published calls for research around the science of UPF, but rather than question the UPF concept, this study looked at how it could be operationalized in different research areas. It considered the interconnected health, environmental, economic and social challenges that occur within food systems. Further, it pointed to the limitations of nutrient-centric approaches in addressing the complexity of diet-health relationships and planetary impacts. While the research took a broader approach to the workshops listed above, it did put the concept of UPFs in context, including review of risk assessment processes.

International Industry Groups: The need for more research on UPF has been expressed by industry. In 2023, one international group (**IAFNS**) published a workshop report addressing the research needs to support the concept of processed foods. This report called for clarifying the impact of processing techniques on nutritional quality and seeing this in contradistinction to product formulations. It also emphasised the importance of safety assessments for food additives. (Trumbo et al. 2024). All these workshops called for greater integration of nutrition and food sciences and technologies.

International Scientific and Professional Bodies: In 2025 the Taskforce on Food Processing for Nutrition, Diet and Health of the International Union of Food Science and Technology (IUFoST) published the IUoFST Formulation and Processing Classification scheme (Ahrné et al. 2025). The purpose was to address confusion and improve the NOVA system and explore other attributes than can be used in food classification such as safety, sustainability, palatability, affordability and convenience. This scheme provided a detailed critique of the NOVA system, pointing out the limitations by focusing on various stages of food formulation and processing and their impact on nutritional value. Further research is required to test this framework. It will require nutrient data before and after processing, and the articulation of processing steps. While not able to deliver an approach to nutrition risk assessment at present, it does provide a pathway for integrating food and nutrition sciences in the future.

At the November 2025 meeting of the Codex Alimentarius Commission, both the IUoFST and Institute of Food Technologists (IFT) called for Codex to engage in a rigorous scientific process to address the classification of healthy foods, enabling

better recognition of healthy foods and dealing with the discrepancies created by the UPF definition. The IUoFST noted the "urgent need for a globally coherent, scientifically sound and transparent approach to food classification", warning of the risks of divergent outcomes to the global community.

Health and Medical Authorities: The broader contextual debate on UPF is also widespread in the health and medical literature. **The Lancet** recently launched the UPF series ranging from nutritional through to political economy aspects of global processed food production (The Lancet 2025).

The first paper in the series presented the nutritional thesis of the UPF movement, that traditional dietary patterns are being displaced by UPF patterns and this is driving the NCD pandemic (Monteiro et al. 2025). This paper included a systematic review of observational studies showing of 104 studies, 94 reported an increased risk of one or more chronic disease outcomes with exposure to an ultra-processed dietary pattern. Significant linear trends were reported in 78 of these 94 studies. Three intervention studies found significant effects of UPF dietary patterns on weight changes. Mechanisms of action were described in terms of deterioration of dietary nutrient profile (although this only partially explained the association), hyper-palatability, disrupted food structures, soft texture, low phytonutrient content, and potentially harmful classes and mixtures of additives. The hypotheses of the UPF thesis were that UPF production is leading to

- global displacement of long-established dietary patterns,
- extensive deterioration of diet quality and
- increasing risk of chronic diseases.

While acknowledging the debates in the literature regarding the need for more research, there was a clear call to consider the *totality* of UPF food substitutions in dietary patterns as this presents the risk to change in dietary patterns.

The American Heart Association also produced a Science Advisory on UPF and their association with cardiometabolic health (Vadiveloo et al. 2025). The AHA reinforced the current dietary guidelines to replace UPFs with healthy whole foods, while noting that not all UPFs are harmful, and indeed many of these are affordable. Those foods that need cutting back are also likely to be foods that are high in salt, sugar and unhealthy fats.

Even so, the report cited critical opportunities for improved monitoring of existing and emerging additives as well as for reductions in certain additives with apparently limited health-related value. Assessments may include machine learning (e.g. with tools such as FoodProX) and inform further regulatory steps. For the USA, the Advisory suggests a phased regulatory approach using nutritional quality to first distinguish UPFs, then focusing on UPFs high in sugar, salt and fat, and finally with specific additives. Ongoing surveillance and mechanistic research would support this effort. Significantly this report calls for a streamlined and efficient evaluation and regulation of food additives

(Vadiveloo et al. 2025). An integrated risk management framework that brings dietary pattern issues into review of food additives may be an important start.

Codex Alimentarius: The topic of UPF was discussed at the November (2025) Codex meeting and all documents are available on the CAC48 webpage* (FAO and WHO 2025).

A range of views were expressed by participants in the meeting and these views were summarised and recorded in the formal report of the meeting thus:

- "There was no clear, science-based, and globally harmonized definition for UPFs, and any definition and/or guidelines should be based on robust scientific evidence.
- There should be transparency in the selection of experts involved in this process, and these should also include food science experts.
- Food classification should be systems-oriented and apply an evidence-based approach.
- There was a need for a common reference point to facilitate productive discussions and effective policy development.
- Codex should consider establishing harmonized definitions for related terms such as novel ingredients and functional foods. "

The FAO encouraged members to look to further FAO and WHO information. As FAO and WHO represent a common reference point, this information would help work on a shared understanding of UPFs. In the meantime, it was noted that there is general interest in this area of work and Members could prepare more detailed proposals for discussion.

4.5 Working Definition of Processed Food

As jurisdictions and organizations seek to respond to emerging epidemiological evidence that the NOVA classification of UPF may need further consideration, it is generally recognised that a working definition of processed foods is required.

At the recent meeting of Codex (November 2025) the World Health Organisation (WHO) confirmed it was developing guidance on the consumption of highly processed foods by two means:

(1) the development of an operational definition of UPF, to provide regulators with an 'intuitive, streamlined method of assessment' of (processed) foods and

(2) guidelines on the consumption of UPF, as noted above.

The composition of a panel of experts from across the globe has been announced to develop a WHO guideline on the consumption of UPFs (WHO 2025). This will provide another important resource for policy and research but may take time given

organizational constraints. There is also recognition that UPF may mean different things to different countries.

In the meantime, there are several ways to move forward. One is to consider the context in which a population consumes food. Research on dietary patterns suggest there is a need to protect healthy cultural food practices. This issue is inherent in dietary guidance, where evidence of the benefits of cultural dietary patterns is considered (for example, the Mediterranean diet). The foods that define these eating patterns are readily identified (some of which may be processed and/or be categorized as UPF), leaving other food categories to be considered in terms of degree and type of processing.

A practical way forward for countries like Australia and New Zealand is to focus on the UPF category of NOVA (Category 4) and develop sub-categories based on nutritional value. This view is consistent with recent local commentary that argues for a greater integration of nutritional and processing status when evaluating foods (Louie 2025)

Finally, there is the question of undertaking risk assessment with sub-populations in mind (including indigenous populations) and how different food categories may be relevant in those circumstances. This may include pre-emptive considerations of sub-populations who may be at further risk with food ingredients not previously ubiquitous in the food supply, for example the impact of sodium replacements with potassium salts and sub populations with renal impairment (Tucker 2025).

Thus, a working definition of processed foods for risk assessment purposes may need to be flexible, allowing for considerations of context and sub-populations. This would also align well with the initial risk governance step of problem formulation.

4.6 Working Definition of Food

On a more principled level, a working definition of food may be needed as a critical reference point. While there are practical realities in food categorization - and the scientific challenges in creating workable distinctions - it may be time for pause to reflect. From a traditional health perspective, food has been recognised as a source of energy, and later of essential chemical components that underpin basic human physiological and biochemical functions. Over time, science exposes an increasing number of these food components and their mechanisms of action. This provides further opportunities for nutrition education, food innovation, and health research, but the concept of food lies at the centre.

First, rather than taking an increasingly reductionist view of food simply as a source of nutrients, a greater appreciation of the inter-relationships between plants, fungi, animals and humans as co-existing entities of Planet Earth augurs well with current concepts of sustainable development. In this very basic sense, food for humans has its origins in other living organisms. As such the chemical composition of these foods reflects the life sustaining molecular pathways, which by nature are interdependent

and reflective of the genetic and environmental conditions under which they survive (Jacobs et al. 2009; Tapsell et al. 2016).

Second, given the 'history of safe use' of food, it seems prudent to think of foods originating from plants and animals as the starting point of working with food and health. Indeed, as human civilisation has evolved, dietary guidelines refer to foods that can be readily identified as 'plant' or 'animal'. Today, the concept of UPF reflects the impact of food innovation on global food production. Following major advances in science and technology, 'processing' now has many dimensions, from physical and chemical interventions to the introduction of new ingredients and additives, making new foods difficult to categorise under traditional systems, and thereby the assessment of effects on dietary patterns and health. Going back to the plant and animal origins of new foods may help in this process. This is done, for example, in the recent analysis of the Australian Nutrition Survey (ABS 2023) where foods are identified in a nutrient-rich group and then as related 'products and dishes' (for example cereals, and cereal products and dishes).

Thirdly, 'natural food' could be considered a starting point for guiding /regulating food innovation involving processing. For example, while there is global recognition that 'breastmilk is best' for newborn infants (WHO), ongoing developments in breastmilk substitutes follow increasing understandings of the chemical composition of breastmilk and its mechanisms of action. Originating from different species, single plant and animal foods will not fit the bill for human nutrition as well as breastmilk, but, given cultural use, their basic formulation can form the starting point for assessing new foods. For example, as environmental concerns for bovine products emerge, processed plant-based milks have been developed. Given the traditional position of diary milks providing essential nutrients in a healthy dietary pattern for the UK population, a rapid review by SACN identified key areas of public health concern with substitutions. In addition, the NOVA classification still proved problematic for plant based milks, with 84% classified as UPF (NOVA 4), 14% processed (NOVA 3) and 2% minimally processed (NOVA 1). (Nowson et al. 2025). This suggests the limitations of NOVA classifications should be considered in assessments of novel foods.

A recently published narrative review of UPF and their animal counterparts argued for the necessity of assessing UPFs against their origins, bearing in mind that they are likely to be analogues of culturally embedded foods. Some of these foods may be more beneficial than their referent counterparts, but it will be necessary to account for specific ingredients and processing level to a assure necessarily nuanced approach (Fernández-Fígares Jiménez and López-Moreno 2025). Further, the idea of 'rational design' for processed foods (Aguilera 2025) could underpin the identification of priorities in nutrition assessment. Here the focus would still be on the delivery of nutrients but with an appreciation that this happens within a food matrix, of which both nutrition and food scientists are developing an increasingly sophisticated view.

4.7 Research Gaps and Future Directions

The panel noted that multiple research gaps require attention to strengthen the evidence on UPF and health. Human studies on food additive exposure and long-term health outcomes are lacking, particularly regarding mixtures and potential cocktail effects. Data on microbiome impacts, food additives, packaging contaminants, and appetite stimulation remain insufficient.

Associations with certain outcomes show weaker evidence requiring further investigation, including asthma, gastrointestinal health, some cancers, and intermediate cardiometabolic risk factors. Studies on non-chronic diseases, children, adolescents, and populations in low- and middle-income countries are limited.

Table 4.2 Research priorities and required methodological improvements

Research priorities	Methodological improvements
Dissecting independent health effects of diet quality versus food processing	Standardization of NOVA classification application across studies
Investigating health impacts of specific ingredients that render UPF categorization	Longitudinal studies with repeated measures in children
Understanding roles of metabolomics and gut microbiome in mediating processing effects	Studies adjusting for dietary patterns and substitution effects
Clarifying which UPF subgroups pose greatest health risks	Multicenter studies across different countries and cultural contexts
Developing objective classification methods that reduce subjectivity	More controlled feeding trials to establish causality
Conducting controlled feeding studies to establish independent effects	Research into mechanisms of ultra-processing

	Environmental sustainability considerations in UPF studies represent an emerging priority, recognizing that health recommendations must balance individual and planetary well-being.

The goal of this research is to provide strong scientific evidence to refine dietary guidance. The research would address the need to discourage nutrient-poor UPFs while clarifying the impact of consuming UPFs compared to foods with more favorable nutritional profiles. This nuanced approach recognizes that in some countries approximately two-thirds of current energy purchased comes from processed or ultra-processed foods, making blanket avoidance recommendations impractical and potentially harmful if they remove affordable sources of nutrients.

4.8 Food Categories identified in FSANZ Materials

The FSANZ website provides clear information to consumers on its approaches to diet quality and food processing (FSANZ 2020; FSANZ 2025). In summary, FSANZ uses a nutrient-based approach to diet quality, notably in policies associated with health star ratings and health claims on individual foods. The approach follows the same principles applied in diet quality scoring systems which have been aligned with healthy eating patterns ascribed to dietary guidelines. The FSANZ page acknowledges the NOVA system of classification (Monteiro et al. 2019), with the four categories.

(1) unprocessed or minimally processed foods,

(2) processed culinary ingredients

(3) processed foods

(4) ultra-processed foods (UPF).

It also notes the research that diets high in UPF are associated with increased risk of death from cardiovascular disease and cancer, but the increased risk of adverse health outcomes was similar to that observed in studies using low food/nutrient scoring systems.

FSANZ has considered NOVA system in previous publications. In her rapid response to the large NutriNet -Sante study (Srour et al. 2019), Mackerras argued that, compared to the lowest quartile, the highest quartile of UPF food consumption produced a higher incidence of cardiovascular disease (HR 1.23, 95% CI:1.04-1.45) but other nutrient profiling indices also produced associations of similar magnitude (Lassale et al. 2016; Liese et al. 2015). She concluded that there are underlying similarities in the nutrient-based and NOVA categorization systems (Mackerras 2019b),

so they both can identify dietary patterns associated with disease risk. However, it should be noted that these studies served epidemiological purposes examining diet-disease relationships with very large population samples and were not focused on single foods.

Epidemiological studies form the basis of evidence review for dietary guidelines, so it is not surprising that UPF are currently being considered. The ADG evidence review underway, and yet to be published, examines the relationship between health outcomes and dietary patterns, as well as the consumption of UPF (NHMRC n.d.). The 2025 US Dietary Guidelines evidence review (DGAC 2025) has been published and examined the risk of cardiovascular disease from food sources of saturated fat and from dietary patterns with UPF. However, the review's final conclusions were that protective dietary patterns were characterised by high intakes of vegetables, fruits, legumes, nuts wholegrains, fish/seafood and oils with high unsaturated fat content, and low in red/processed meat, sugar rich foods and beverages, refined grains and saturated fats. Thus, while the concept of UPF was considered, the outcomes emerged, not in terms of UPF categories but rather nutrient rich food groups to recommend and otherwise nutrient defined food groups to limit.

This suggests that the nutrient-based categorization of foods still serves the evidence framework for dietary guidelines purposes. Nevertheless, a watching brief on UPF is warranted as new research emerges. For example, a systematic review of UPF classifications, notes that risks associated with additives may be a further consideration, rather than just their mere presence (Medin et al. 2025).

In a separate analysis Mackerras (Mackerras 2019a) examined the concordance between the NOVA categories and the nutrient-based categories of the ADG, when analysing dietary intakes from the 2011-2012 Australian National Nutrition and Physical Activity Survey. After classifying the 5645 foods in the database according to these systems, 4014 were ADG recommended foods, but of these 23.5% were classified as UPF. On the other hand, 31.2% of the ADG 'discretionary' foods were classified as *not* UPF. Thus, at a food level there are important differences between the food categorization systems, if indeed the translation requires advice to limit UPFs in some forms. This has implications for regulatory policies related to nutrition aligned to the ADG.

Lack of agreement between categorization systems is a recognised problem, but there may be a way forward with novel approaches to research. In a study of data on 33,054,687 foods purchased by US households (using data from Nielsen IQ), Popkin and colleagues found a lack of agreement between the two methods (HFSS – nutrient based; UPF) which was highly significant ($P<0.0001$). However, by combining HFSS criteria and adding elements of UPF, agreement could be achieved (Popkin et al. 2024). This methodology could prove useful in identifying less healthy foods from both perspectives. It also raises new research questions: are the dietary associations with NCDs stronger when these foods that are both HFSS and UPF are examined, and is there any indication of less harm with foods that are UPF but not HFSS, or vice versa?

Dealing with processing itself is another consideration. Consumer information on the FSANZ website describes processed foods as those modified from their original fresh or whole state. Processing includes freezing, canning, drying, preserving, fermentation, with other techniques including the use of additives and preservatives, high pressure cooking, frying, dehydration, purification, heat treating and chemical modification. Foods are listed as processed, ADG recommended food categories, and ADG 'discretionary' foods, that are high in fat, sugar and salt (HFSS). Differences and similarities show some of the challenges for risk assessment, especially for the grains category of foods (Table 4.3).

The Food Standards Code as it appears on the website (FSANZ n.d.) appears in two parts, the first dealing with nutrition policy positions and processing, and the second with food categories. Details in Part 1 of the Code, include: Labelling and other information requirements (including health claims); Substances added to or present in food (including additives, processing aids, nutrients); Contaminants and residues; Foods requiring pre-market approval (including novel foods); Microbial limits and processing requirements.

These issues appear separate to the Food categories that appear in Part 2. Food categories regulated by the Code are listed as Cereal and Cereal Products (Bread & bread products; Wholegrain cereals & cereal products); Meats, eggs, fish (including products); Fruit and vegetables (including jam); Edible oils (including spreads); Dairy products (full range); Non-alcoholic beverages (4 types); Alcoholic beverages (5 types); Sugars and honey; Special purpose foods (including infant, sports, medicinal, supplementary); Others (vinegar, salt, gum, miscellaneous). (Table 4.3)

Table 4.3 Food categories listed on FSANZ 'Food Processing' consumer webpage

Food Standards Code Category	ADG recommended	Processed	ADG discretionary
Cereal and cereal products	Grains, mostly wholegrain/high fibre	Bread Breakfast cereals Cakes and biscuits	Biscuits and cakes Pastries
Vegetables	Vegetables	Chips Tinned vegetables	Potato chips
Fruit	Fruit	Tinned fruit	
Dairy products	Milk	Milk drinks	

	Cheese Yoghurt	Cheese	
Meat, eggs, fish	Lean meats/poultry, fish, eggs, nuts, seeds, tofu, legumes, beans	Pies Sausage rolls Meat products	Pies Commercial burgers Processed meats
Special purpose foods		Ready to eat meals	Pizzas
Edible oils			Fried foods
Non-alcoholic beverages	Water	Soft drinks	Sugar-sweetened beverages
Alcoholic beverages			
Sugars and honey			Confectionary
Others			

At the top level, there is partial alignment of food categories between representations of the Food Standards Code and the ADG. Food groups recommended in the ADG tend to be unprocessed, whereas discretionary foods align with processed grain-based foods and meats, and soft drinks. This mapping out of food categories may help in identifying potential problems for dietary patterns and developing analytical strategies for risk assessment.

Some dilemmas may arise with ADG recommended foods. For example, bread and cheese are both recommended and processed, reflecting their nutrition contributions and cultural use in the Australian context. This is where some flexibility in food categorisation may be required, as suggested earlier (see 4.5). This is the case, for example, in food labelling conditions, where nutrient profiling is considered at a food category level.

4.9 Implications for FSANZ processes

The panel considered the ways in which approaches to food categorization impacted upon risk assessment for public health, notably through the processes of applications and proposals. The panel considered how a more integrated problem-oriented approach to assessments might also utilise some of the insights from the consideration of food categorization.

The example of plant-based 'milks' was discussed at length where a processed food category appeared to be successfully replacing a commodity food. While it is hard to predict the degree of market penetration of a novel food, this example highlighted the value of consumer insights, food safety and nutrition working together in initial problem formulations, especially around novel foods. It also raised the possibility of post market-surveillance. This could acknowledge industry responsibility, given their stewardship role and the social license of applicants.

The panel heard that currently novel foods tend to be managed by the New Foods team under the Food Safety group. The nutrition team could provide a member, but the team itself manages issues relating to nutritive substances. It is rarely involved in applications for processing aids. The nutrition input into novel foods assessment is also nutrient focused, considering impacts on intakes. Thus, the panel noted that while adequacy and toxicology are considered, these are chemically based concerns, and there appeared to be no remit to holistically consider the nature of the food(s) nor impact on dietary patterns.

Likewise, the panel heard that the dietary exposure assessment team characterises the diet in terms of nutrient combinations, not foods or dietary patterns. The focus is on formulation and composition, not behavioural and other impacts. Nevertheless, the panel noted the resources and capability are there to unpack the issues around discretionary foods with comprehensive databases, skills in dietary modelling and the potential offered by generative AI.

The panel considered that new questions could be considered when receiving applications such as: How is this process/ novel food related to discretionary food categories that appear highly consumed in populations and are associated with poor dietary patterns? How are the formulations of these foods likely to impact higher sugar, saturated fat or sodium intakes in the population? What potential dietary patterns may emerge and how do they align with those associated with increased risk of non-communicable disease?

Overall, it was clear to the panel that the teams in FSANZ are highly skilled, engaged and well informed, bearing the capacity to pivot to an integrative public health risk assessment framework. A FSANZ proposal to move in this direction could be considered, with the added benefit of stakeholder consultation an integral part of the process.

4.10 Summary and Conclusions

Food categorization is a critical element in examining the food-health relationship and therefore for nutrition risk assessment in food regulation. Traditional forms of food categorization have focused on the nutrient components, but more recent approaches have focused on the level of food processing (including the use of additives). Of particular interest has been the NOVA categorisation of foods, introducing the concept of Ultra Processed Foods (UPF).

This chapter addressed the strengths and limitations of nutrient-based vs process-based food categorizations and found they may not be mutually exclusive. Rather, they may reflect different ends of a spectrum. It may be that nutrient-focused categories best identify foods to recommend but processed-based categories better identify foods to limit.

Food categorization for risk assessment purposes may need to be flexible, allowing for considerations of context and sub-populations. This would also align well with the initial risk governance step of problem formulation.

Traditional nutrient-based food categories are used in dietary guidelines, but the panel further considered whether the emergence of UPF categories take the guidelines further, with possible implications for food regulators. In the first instance, comparing food categories utilised by dietary guidelines and in Food Standards may help to identify foods under consideration that are potentially problematic for healthy dietary patterns. This awareness may be incorporated into questions for problem formulation and subsequent analytical strategies for risk assessment. For example, where risk assessment involves foods such as discretionary cereal-based products and processed meats, the impact on healthy dietary patterns may need to be considered.

One of the reasons for this extra attention is that poor adherence to dietary guidelines appears to be remain a global problem, possibly reflecting ongoing shifts in the food supply. Food product innovation is ongoing, including reformulation and processing. This also means the composition even of basic foods changes relatively rapidly. Regulatory decisions may passively increase the supply of discretionary foods by not adequately fully addressing nutrition issues, leading to undue influence on healthy dietary patterns.

To that point, nutritional risk assessment needs to consider how current regulatory processes address the impact of approvals, for example, for processing aids and novel foods, in terms of their likely impact on healthy/unhealthy dietary patterns and the food supply. The concepts inherent in the UPF categorisations may be considered in subsequent analytical approaches, particularly dietary exposure assessment.

These same issues were raised in discussions with international counterparts, where ongoing food innovation and the concept of UPF were seen as challenging nutrition risk assessment and dietary guidance.

The international community is actively engaged in these developments, with workshops, meetings and advisory publications debating issues of science and its application. There is a clear indication that processing needs to be incorporated into food categorizations, but there are significant challenges ahead. To begin with, better integration of nutrition and food sciences in food innovation, and of food safety and nutrition in risk assessment would be productive. This also warrants clear working definitions of processed foods, and indeed of food itself.

Global positions on food are also necessary, given the potential impact of food regulation standards on global health and trade. The Codex Alimentarius Commission has the mandate, as well as the necessary breadth of connections across jurisdictions and sectors along with the scientific input of FAO and WHO expertise. There are opportunities for FSANZ to utilise these already well-established relationships to work on the issues raised in this chapter on food categorisation.

In summary, nutrition assessment needs to move beyond standard toxicology to consider the long-term consequences of foods consumed within dietary patterns. Analytical processes can use both processed and nutrient-based approaches where appropriate. In other words, food categorization in nutrition risk assessment can be flexible depending on the question. The main issue is whether nutrition is considered at the problem identification stage.

Future best practice is likely to see fully integrated components of risk assessment in food regulation, overcoming issues related to different capacities, limitations of methodologies, and institutional boundaries. FSANZ appears well positioned to take the lead in this change. Questions relating to impacts on dietary patterns are addressed at the initial problem formulation stage, and food categorization would play a part of this process.

References for Chapter 4

ABS (2023) Food and Nutrients, ABS Website, Canberra. https://www.abs.gov.au/statistics/health/food-and-nutrition/food-and-nutrients/latest-release#selected-micronutrients-and-caffeine. Accessed 16 April 2026.

Aguilera JM (2025) Food matrices as delivery units of nutrients in processed foods, *Journal of Food Science*, 90(2), e70049, doi:10.1111/1750-3841.70049.

Ahrné L, Chen H, Henry, CJ, Kim HS, Schneeman B and Windhab EJ (2025) Defining the role of processing in food classification systems—the IUFoST formulation & processing approach, *npj Science of Food,* 9(1):56, doi:10.1038/s41538-025-00395-x.

Australian Government (2025) Strategic Plan 2025–2028, Australian Government, Canberra. https://www.foodregulation.gov.au/sites/default/files/2025-08/strategic-plan-2025-2028_0.pdf

Bernstein JT, Brown AW, Burton-Freeman B, Estevez M, Hess JM, Hubert PA and Latulippe ME (2026) Guiding Principles for Science-Based Food Classification Systems Focused on Processing and Formulation, *Advances in Nutrition*, 17(4):100577, doi:10.1016/j.advnut.2025.100577.

CDC (National Center for Health Statistics) (2025) Ultra-Processed food consumption in youth and adults: United States, August 2021-August2023, National Center for Health Statistics, United States. https://www.cdc.gov/nchs/products/databriefs/db536.htm. Accessed 16 April 2026.

CIHR (Canadian Institutes of Health Research) (2024) Unpacking ultra-processed foods: Identifying research priorities, Virtual Best Brains Exchange summary, Canadian Institutes of Health Research, Ottawa. https://cihr-irsc.gc.ca/e/54277.html. Accessed 15 April 2026.

DGAC (Dietary Guidelines Advisory Committee) (2025) Scientific report of the 2025 Dietary Guidelines Advisory Committee, United States Government, Washington. https://www.dietaryguidelines.gov/2025-advisory-committee-report

EFSA (European Food Safety Authority) (n.d.) Methods for evidence use in scientific assessments, European Food Safety Authority, Parma. https://multimedia.efsa.europa.eu/prometheus/index.htm. Accessed 16 April 2026.

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson JL, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArdle HJ, Naska A, Neuhäuser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Sjödin A, Stern M, Tomé D, Van Loveren H, Vinceti M, Willatts P, Martin A, Strain JJ, Heng L, Valtueña Martínez S and Siani A (2017) Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 2), *EFSA Journal 2017*,15(1):4680, doi:10.2903/j.efsa.2017.4680.

EFSA NDA Panel (2021) Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013, *EFSA Journal,* 19, doi:10.2903/j.efsa.2021.6544.

Eurofins (2024) Nutri-Score – all important facts and novelties at a glance, Eurofins, Leipzig. https://www.eurofins.de/food-analysis/other-services/nutri-score/. Accessed 15 April 2026.

FAO and WHO (2025) Codex Alimentarius Commission meetings. Codex Alimentarius: November (2025) Codex meeting [CAC48 webpage]. https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CAC&session=48

Fernández-Fígares Jiménez MDC and López-Moreno M (2025) Ultra-processed Plant Foods: Are They Worse than their Unprocessed Animal-Based Counterparts?, *Current Nurition Reports*, 14(1), doi:10.1007/s13668-025-00704-6.

FSANZ (n.d.) The Food Standards Code legislation, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/food-standards-code/legislation

FSANZ (2020) Diet quality and processed foods, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/consumer/nutrition/Diet-quality-and-processed-foods

FSANZ (2025) Processed foods, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/consumer/our-safe-food-supply/processed-foods

Jacobs DR, Gross MD, Tapsell LC (2009) Food synergy: an operational concept for understanding nutrition, *American Journal of Clinical Nutrition*, 89(5):1543S-1548S, doi:10.3945/ajcn.2009.26736b.

Lassale C, Gunter MJ, Romaguera D, Peelen LM, van der Schouw YT, Beulens JWJ, Freisling H, Muller DC, Ferrari P, Huybrechts I, Fagherazzi G, Boutron-Ruault MC, Affret A, Overvad K, Dahm CC, Olsen A, Roswall N, Tsilidis KK, Katzke VA, Kühn T, Buijsse B, Quirós JR, Sánchez-Cantalejo E, Etxezarreta N, Huerta JM, Barricarte A, Bonet C, Khaw KT, Key TJ, Trichopoulou A, Bamia C, Lagiou P, Palli D, Agnoli C, Tumino R, Fasanelli F, Panico S, Bueno-de-Mesquita HB, Boer JMA, Sonestedt E, Nilsson LM, Renström F, Weiderpass E, Skeie G, Lund E, Moons KGM, Riboli E and Tzoulaki I (2016) Diet Quality Scores and Prediction of All-Cause, Cardiovascular and Cancer Mortality in a Pan-European Cohort Study, *PLoS One*, 13;11(7):e0159025, doi:10.1371/journal.pone.0159025.

Liese AD, Krebs-Smith SM, Subar AF, George SM, Harmon BE, Neuhouser ML, Boushey CJ, Schap RE and Reedy J (2015) The dietary patterns methods project: synthesis of findings across cohorts and relevance to dietary guidance, *The Journal of Nutrition*, 145:393-402, doi:10.3945/jn.114.205336.

Louie JCY (2025) Are all ultra-processed foods bad? A critical review of the NOVA classification system, *Proceedings of the Nutrition Society*, 4:1-9, doi:10.1017/s0029665125100645.

Machado P, Russell C, de Melo PR, Baker P and Lawrence M (2025) Research roadmap for ultra-processed foods in the context of the Australian food system. *Nutrition & Dietetics*, 82(5):587-601, doi:10.1111/1747-0080.70018.

Mackerras D (2019a) Mis-match Between the Healthy Food and the Ultra-processed Food Classifications in Australia (OR14-03-19), *Current Development in Nutrition*, 3, doi:10.1093/cdn/nzz038.OR14-03-19.

Mackerras D (2019b) Rapid Response: Is NOVA unique in being associated with health outcomes?, *BMJ*, 365:11451, doi:10.1136/bmj.l1451.

Medin AC, Gulowsen SR, Grouth-Jacobsen SG, Berget I, Grini IS and Varela P (2025) Definitions of ultra-processed foods beyond NOVA: a systematic review and evaluation, *Food & Nutrition Research*, 69: 12217, doi:10.29219/fnr.v69.12217.

Monteiro CA, Cannon G, Levy RB, Moubarac JC, Louzada ML, Rauber F and Jaime PC (2019) Ultra-processed foods: what they are and how to identify them, *Public Health Nutrition*, 22(5):936-941, doi:10.1017/s1368980018003762.

Monteiro C, Louzada MLC, Steele-Martinez E, Cannon G, Andrade GC, Baker P, Bes-Rastrollo M, Bonaccio M, Gearhardt AN, Khandpur N, Kolby M, Levy RB, Machado PP, Moubarac J, Rezende LFM, Rivera JA, Scrinis G, Srour B, Swinburn B and Touvier M (2025) Ultra-processed foods and human health: the main thesis and the evidence, *The Lancet*, 406(10520):2667-2684, doi:10.1016/S0140-6736(25)01565-X.

More SJ, Benford D, Hougaard Bennekou S, Bampidis V, Bragard C, Halldorsson TI, Hernández-Jerez AF, Koutsoumanis K, Lambré C, Machera K, Mullins E, Nielsen SS, Schlatter J, Schrenk D, Turck D, Naska A, Poulsen M, Ranta J, Sand S, Wallace H, Bastaki M, Liem D, Smith A, Ververis E, Zamariola G and Younes M (2024) Guidance on risk-benefit assessment of foods, *EFSA Journal,* 22(7):e8875, doi:10.2903/j.efsa.2024.8875.

NHMRC (n.d.) Reviewing the evidence, National Health and Medical Research Council, Canberra. https://www.nhmrc.gov.au/health-advice/nutrition/australian-dietary-guidelines-review/reviewing-the-evidence

Nowson GK, Fallaize R and Earl KE (2025) Exploring the Nutritional Profile and Cost of Plant-Based Milk Alternatives Compared with Dairy Milk in the UK with Consideration of Environmental Impact Data, *Current Developments in Nutrition*, 9(6):107436, doi:10.1016/j.cdnut.2025.107436.

O'Connor LE, Higgins KA, Smiljanec K, Bergia R, Brown AW, Baer D, Davis C, Ferruzzi MG, Miller K, Rowe S, Rueda JMW, Andres A, Cash SB, Coupland J, Crimmins M, Fiecke C, Forde CG, Fukagawa NK, Hall KD, Hamaker B, Herrick KA, Hess JM, Heuven LA, Juul F, Malcomson FC, Martinez-Steele E, Mattes RD, Messina M, Mitchell A and Zhang FF (2023) Perspective: A research roadmap about Ultra-Processed Foods and human health for the United States food system: proceedings from an inter-disciplinary, multi-stakeholder workshop, *Advances in Nutrition*, 14(6):1255-1269, doi:10.1016/j.advnut.2023.09.005.

Popkin BM, Miles DR, Taillie LS, Dunford EK (2024) A policy approach to identifying food and beverage products that are ultra-processed and high in added salt, sugar and saturated fat in the United States: a cross-sectional analysis of packaged foods. *The Lancet Regional Health – Americas*, 32, doi:10.1016/j.lana.2024.100713.

SACN (2025a) SACN statement on the WHO guideline on non-sugar sweeteners, Scientific Advisory Committee on Nutrition, London. . Accessed 16 April 2026.

SACN (2025b) Processed foods and health: SACN's rapid evidence update summary, UK Government, London. https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update/processed-foods-and-health-sacns-rapid-evidence-update-summary. Accessed 16 April 2026.

SACN and COT (Scientific Advisory Committee on Nutrition and Committee on Toxicity) (2025) SACN and COT assessment of the health benefits and risks of consuming plant-based drinks: summary, UK Government, London. . Accessed 16 April 2026.

Srour B, Fezeu LK Kesse-Guyot E, Allès B, Méjean C, Andrianasolo RM, Chazelas E, Deschasaux M, Hercberg S, Galan P, Monteiro CA, Julia C and Touvier M (2019) Ultra-processed food intake and risk of cardiovascular disease: prospective cohort study (NutriNet-Santé), *BMJ*, 365:l1451, doi:10.1136/bmj.l1451.

Tapsell LC, Neale EP, Satija A, Hu FB (2016) Foods, nutrients and dietary patterns: interconnections and implications for dietary guidelines, *Advances in Nutrition,* 7(3):445-454, doi:10.3945/an.115.011718.

The Lancet (2025) Ultra Processed Foods and Human Health Series, *The Lancet*, London. https://www.thelancet.com/series-do/ultra-processed-food

Trumbo PR, Bleiweiss-Sande R, Campbell JK, Decker E, Drewnowski A, Erdman JW, Ferruzzi MG, Forde CG, Gibney MJ, Hess JM, Klurfeld DM, Latulippe ME, O'Connor LE, Reimers KJ, Rolls BJ, Schulz J, Weaver C and Yu L (2024) Toward a science-based classification of processed foods to support meaningful research and effective health policies, *Frontiers in Nutrition*, 11:1389601, doi: 10.3389/fnut.2024.1389601.

The Lancet (2025) Ultra Processed Foods and Human Health Series, *The Lancet*, London. https://www.thelancet.com/series-do/ultra-processed-food

Tucker KL (2025) Is it time to take a closer look at ultra processed foods?, *The American Journal of Clinical Nutrition*, 121(4):752-753, doi:10.1016/j.ajcnut.2025.02.007.

Vadiveloo MK, Gardner CD, Bleich SN, Khandpur N, Lichtenstein AH, Otten JJ, Rebholz CM, Singleton CR, Vos MB and Wang S (2025) Ultra processed Foods and Their Association With Cardiometabolic Health: Evidence, Gaps, and Opportunities: A Science Advisory From the American Heart Association, *Circulation*, 152:e245–e263, doi:10.1161/CIR.0000000000001365.

WHO (2025) Call for experts to develop a WHO guideline on consumption of ultra-processed foods, World Health Organisation, Geneva. https://www.who.int/news-room/articles-detail/call-for-experts-to-develop-a-who-guideline-on-consumption-of-ultra-processed-foods

CHAPTER 5: NATIONAL NUTRITION SURVEYS

5.1 Introduction

With the recent release of data on foods consumed by Australians, the panel considered how greater use of nutrition surveys might enhance efforts in public health risk governance. A focused review was undertaken to identify opportunities to best utilise these surveys and other potential resources.

Nutrition risk assessment (NRA) is an evidence-driven process which references dietary guidelines and standards for nutrient requirements. National Nutrition Surveys (NNS) provide evidence of population food consumption patterns which may be evaluated for concordance with dietary guidelines and adequacy of nutrient intake. As dietary guidelines are underpinned by evidence of the diet-disease relationship with non-communicable diseases (NCDs), analysis of NNS gives an indication of the degree of protection afforded by dietary pattens, and indirectly the food supply. Thus, NNS are a valuable resource for risk governance addressing NCDs.

The limitations of NNS need to be considered, not least given the constantly changing food supply which presents with ongoing challenges both in terms of timely responses to food innovations and maintenance of relevant food databases. The underpinning dietary data used in NNS are subject to well-recognized limitations in the current generation of methods, with its main reliance on 24-hour recalls and other tools for self-reporting. NRA that draws on NNS needs to interpret apparent alignment or misalignment with dietary guidelines considering these method-related biases, which may differ by age, sex, BMI and other sociodemographic characteristics. Despite these limitations, NNS have a significant role to play in a food regulation environment characterised by the rapid emergence of new foods that impact on the food supply.

The key question for the panel is how can NNS and other dietary exposure data be best utilized to assist in an extended view of public health risk governance?

5.2 Methodology

The FSANZ publication 'Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes' served as a primary reference point (FSANZ 2024a). Noting that exposure assessments in that publication focused on nutrient intakes, the panel considered how NNS data on foods consumed might form part of problem formulation relating to dietary patterns. The panel looked at evidence from the Australian NNPAS (2023-2024) that identified foods that accounted for poor alignment with dietary guidelines (ABS 2025). Given the infrequent conduct of NNS the panel identified gaps in dietary monitoring, using the example of the introduction of plant-based milks into the market. As food databases underpin analyses of NNS, the panel also considered

how different data streams may be of benefit. Conclusions and recommendations were embedded with insights from meetings with FSANZ members.

5.3 National Nutrition Surveys and Problem Formulation

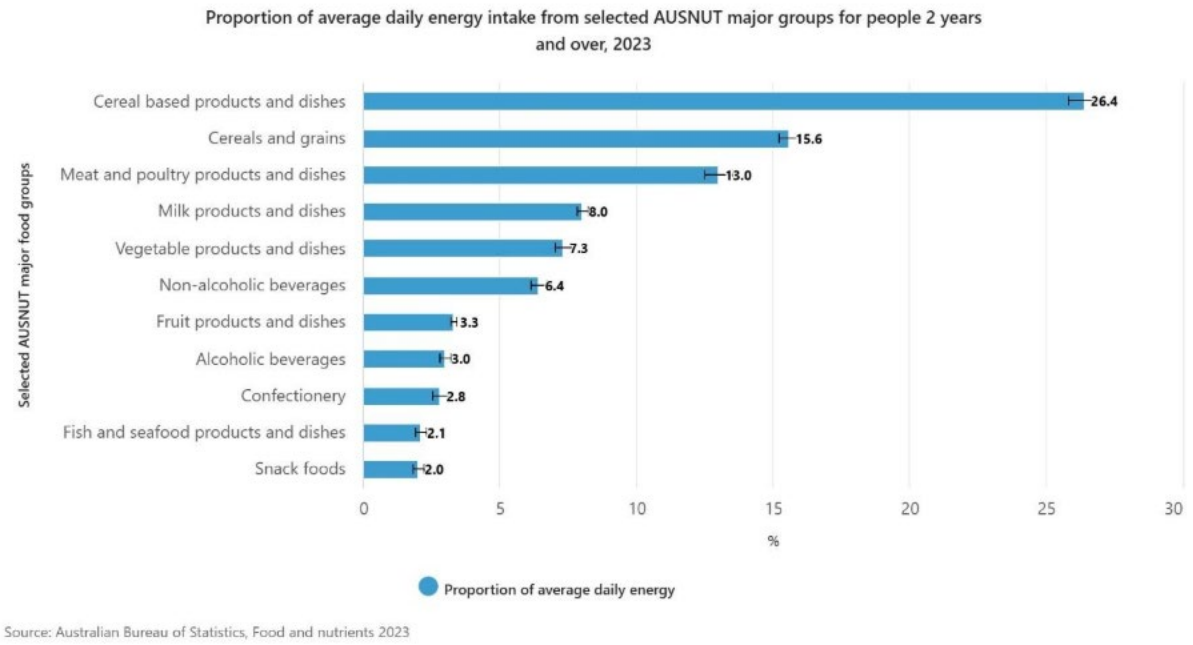
Analyses of NNS are a useful tool for problem formulation. For example, in the interviews with international counterparts the panel heard that the UK utilizes national diet and nutrition surveys to identify populations at risk and nutrients of concern. This contributes to the identification of priorities for risk assessment. Once priorities are determined, it remains to scope the issue, characterize the risk, formulate the problem and initiate the process of evidence-based assessment. Where a nutrient is the starting point, the approach may be directed towards, for example, the impact of food fortification on the incidence of disease (as with folate/flour and the prevention of neural tube defects, NTDs). Where new foods are introduced, the approach may be to consider the case against a referent model, for example comparing the nutritional impact of plant-based milks replacing cow's milk using dietary modelling techniques.

NNS, conducted separately in Australia and New Zealand can enable proactive steps in risk governance. For example, as discussed below, recent analyses of the NNS produced by the Australian Bureau of Statistics (ABS) can help to identify foods that are relevant to dietary guidelines, and this evidence can be used in public health risk governance. Current reported areas of concern include the contribution of food categories to energy intake, food sources of protein and shifts in dietary fat sources.

5.3.1 Food sources of energy

Unhealthy dietary patterns result from excessive energy intakes, and are characterized by foods rich in added sugar, salt and fat. Known as discretionary foods, these generally align with the ultra-processed food category in the NOVA classification (see Chapter 4 for further discussion) and, under the dietary guidelines, come with recommendations to limit. In nutrition risk assessment, they would be foods to watch in terms of impacts on healthy dietary patterns.

In the recently released ABS report on the latest Australian NNPAS (2023-2024) (ABS 2025) discretionary foods were major contributors to energy intakes. The data showed discretionary food intake was reported as just under one third (31.3%) of energy intake for Australians aged 2 years and over. These foods are embedded within broader food categories.



Of the cereal based products and dishes category about a third of this (10.9% energy) was contributed by discretionary foods: cereal-based mixed dishes, sweet biscuits, pastries, cakes/muffins/desserts. That was 3 times more than other discretionary food categories, although the contribution from snack foods had increased from the previous survey 2011-12. For most of the population this proportion of energy consumed from discretionary foods suggests poor diet quality, particularly in those with low energy requirements.

The value of these analyses lies in the provision of evidence regarding foods that may pose a risk to dietary patterns especially if they replace healthy foods. The context in which this knowledge could be applied includes assessments of new applications for novel foods or processing aids, as well as related regulatory measures. Problem formulation for public health risk could consider the impact of potentially driving discretionary food production. The current ABS analysis indicates cereal-based products and dishes are a category of foods to watch.

5.3.2 Food sources of protein

Plant based foods are being encouraged in dietary guidelines and this has been followed by innovations in plant-protein rich products. Thus, watching briefs are warranted on how protein-rich plant food substitutions might affect nutritional intakes. The ABS analysis showed that while the absolute amount of protein consumed remained steady, it increased in males aged 12-17years with the main food sources for this group of consumers remaining traditional foods: cereal based mixed dishes (19.6%; e.g. sandwiches, pasta, pizza), meat and poultry (7.5%), bread (4%) and dairy milk (4.0%).

Food innovation using plant-based proteins may change this pattern of consumption as they enter the market. One of the issues to address with analogues of traditional protein rich foods will be whether they replace the traditional foods' full nutrient contribution, notably key vitamins and minerals. Additional dietary monitoring may be required, with the NNS providing interval data in support of problem formulation for risk governance.

5.3.3 Food sources of fat

Advice to reduce saturated fat intakes has been part of dietary guidelines for decades. Initial attempts at reducing dietary fat targeted fatty meats and full fat dairy products, with associated food innovations. With the highly varied food supply of today, however, the recent ABS analysis showed that intakes of saturated fat increased from 12.4% to 13.0% of energy. This is above the WHO guideline and raises concerns for both food innovation and regulation.

Significantly, 39.9% of the total saturated fat plus trans fat came from discretionary foods, not core foods, suggesting a shift from the initial focus on commodity products (i.e. fatty meats and full fat dairy products). Instead, the problem appears to now lie with discretionary foods.

For dietary fat, cereal based mixed dishes topped the list again: they were the highest contributor to fat intake (17.0%), followed by poultry-based mixed dishes (5.0%), potatoes and potato-products dishes (4.7%) and pastries (4.9%). Rather than commodity products like meat and dairy foods, these are all composite foods. It is important to also note that the contribution of these discretionary foods was greater than that of nutrient dense foods advocated in dietary guidelines such as dairy milk (4.9%), nuts and nut products (3.8%) unprocessed meats and cheese (each 3.1%). These have clear implications for nutrition risk governance.

5.3.4 Utility of NNS in problem formulation

Together, these analysis of the NNS show that discretionary foods play too large a part in the Australian diet and are becoming a major source of saturated fat, intakes of which are increasing beyond health guidelines. Shifts in protein sources are not yet felt as consumers are still consuming protein from traditional foods, but change is likely happening alongside food innovations in plant-based products. Given these observations, questions may need to be asked in relation to approvals for novel foods, ingredients and processing techniques. This takes nutrition risk assessment beyond traditional chemical risk assessment, to food based dietary pattern risk assessment. Pro-active considerations of the impacts of classes of foods and processing aids/technologies may be needed at the initial problem formulation stage.

5.3.5 Limitations of NNS

The 24-hour recall and other recall methods used in the NNS are prone to systematic underreporting of energy intakes, recall errors and culture/social desirability bias. The under estimation of energy intake can range from about 4 to 37% in validation studies (Boushey et al. 2016), and they require multiple survey days to approximate usual intake for irregularly consumed foods.

The literature on new dietary assessment methodologies argues for more agile, technology-supported surveillance (e.g. online 24-hour recalls, app-based food records, or linkage to retail sales data) that can provide interim intelligence between full NNS rounds. For NRA, such agility is particularly important where novel foods could materially alter intakes of nutrients of concern (e.g. iodine or vitamin B12).

From a methodological perspective, problem formulation informed by NNS should also explicitly consider where the current survey design is strong or weak for a given question. For example, questions about discretionary food categories that are consumed frequently (e.g. sweet biscuits) are better supported by 24-hour recall data than questions about rarely eaten foods, where usual-intake estimation becomes more uncertain. Likewise, if certain age groups or cultural communities are underrepresented, then NNS-derived priorities could inadvertently understate risk in those populations. Framing these limitations explicitly at the problem-formulation stage helps to calibrate subsequent NRA steps and can motivate targeted supplementary data collection where needed.

The broader methodological literature increasingly supports this type of multi-source integration. Food balance sheets, retail scan data, online 24-hour recall tools and targeted surveys each capture different aspects of intake and product availability and combining them through market-weighted or scenario-based modelling can partially offset weaknesses in any single source. In the future, NRA could further leverage technology-assisted individual tools (e.g. web- or app-based recalls with automated coding) to generate more frequent but lighter-touch updates that can be linked to these complementary datasets.

5.4 Dealing with the ever-changing food supply

Public health risk governance needs to deal with the ever-changing food supply. NNS data can provide snapshots at a point in time, but the success of new products in infiltrating the diet is unknown. In some cases, significant changes occur before the next round of NNS, with implications for the risk governance framework.

New foods may be approved for market but their impact on dietary patterns may only become apparent later. New problems for risk governance may then arise. An example lies with plant-based beverages. With dietary guidance tending toward a more plant-based diet, food innovations such as cow's milk analogues have emerged. The UK SACN review of plant-based milks found that at this time, plant-based beverages could

not be recommended as a replacement for dairy milk on nutritional grounds, including a lack of consistency in nutritional profiles (Nowson et al. 2025).The findings were congruent with a study of 219 dairy milk alternatives from 21 brands available in the US (Johnson et al. 2025) which found that most products were not nutritionally equivalent to dairy milk and that nutrient variability was high. Likewise, an Australian audit of 129 plant-based milk products found most products were nutritionally different to cow's milk, with wide variation in nutrient content (Harmer et al. 2024). Although soy milk and cow's milk contained similar amounts of protein, and 80.6% of products were fortified with calcium, there was wide variation in other nutrients of concern were iodine, phosphorus, zinc and vitamins A, B2 and B12. It is important to note that these concerns also reflect current knowledge of the value to human nutrition of a naturally occurring food (cow's milk).

The differences in nutrient composition represents an initial problem with product formulation that could have been addressed at the approval stage, for example, by formulation guidance or a food standard, had consumer behaviour been predicted. It also suggests a lack of understanding by food innovators of what might be required in the first place. While nutrient adequacy/deficiency can be addressed with comparisons of nutrient delivery from traditional and analogous foods, these analyses do not address the issue of health benefits of the food itself, nor their significance in a recognised dietary pattern associated with reduced disease risk. While the mechanisms of action of ingredients appear favourable, the scientific evidence from clinical and observational studies of the food and associated dietary patterns is often lacking. Best practice would also demand independent systematic review of the body of evidence with quality measures, such as using the GRADE approach.

The case of plant-based milks exemplifies the disjuncture between food innovation and evidence-based science, where products emerge from an aspect of dietary guidance, but the evidence of the full extent of the diet-disease relationship is not addressed. A gap arises when the products are already developed, but the population-based research would take years.

Even so, a sustainable, integrative position of dietary guidance is reflected in the shift towards a more plant-based diet, so a degree of flexibility may be required. At the most basic level, however, meeting requirements for nutrients cannot be compromised, so current assessment practices remain critical, but more is needed.

Additional requirements mean nutrition science needs to evolve with innovation. A recent review recognises that food innovation is moving food choices from culturally embedded animal foods to plant-based alternatives. In this scenario, science requires better defined food and dietary controls in research, and a nuanced understanding of how processing and formulation of plant-based foods may be approached. This includes attention to food composition tables where ingredients (formulation) and degree of processing are distinguished (Jiménez and López-Moreno 2025). Processing may provide a pathway to more plant-based diets, alongside dietary patterns with

more minimally processed (naturally occurring) plant foods and less animal foods. These issues can be raised in problem formulation stages of risk governance.

From the survey perspective, NNS, coupled with updated branded-food databases, are critical to tracking how quickly these plant-based analogues penetrate the market, which sub-groups are adopting them, and the net effect on nutrient intakes. However, the traditional survey model of large, infrequent cross-sectional studies, struggles to keep pace with rapid innovation cycles. One way of dealing with the pace of product innovation more flexibly is to introduce targeted post-market monitoring of new product categories where there is a likelihood of substantial change. Consumer insights surveys can target questions to help identify trends and other forms of data may be collected across a time course relevant to the pace of change of dietary habits. This brings manufacturers' sales and market data into play, as one of the significant additions to the toolkit for dietary exposure assessment.

5.5 Expanding food composition databases

With a broader approach to food intake monitoring, manufacturers' food databases become increasingly relevant. The landscape in dietary assessment points toward closer integration between NNS, branded-food databases, and external digital data streams (e.g., scanner data and online platforms). Reviews of technology-based assessment methods highlight the potential of web-based 24-hour recall tools and image-assisted methods to generate richer, more disaggregated product information, especially when linked to up-to-date branded databases. For risk governance, this opens pathways to more dynamic mapping of foods across multiple classification schemes (e.g. ADG food groups, HFSS, UPF, "healthy" label criteria), but it also increases the demand for harmonized taxonomies and interoperable coding systems.

5.5.1 FSANZ food composition databases

Food composition data is used in all forms of dietary research and underpins the analyses of National Nutrition Surveys (NNS). In dietary exposure assessment, FSANZ uses several sources of food composition data (FSANZ 2024b). FSANZ is responsible for the Australian Food Composition Database and the files that estimate intakes from NNS (AUSNUT). In addition, FSANZ is developing the Australian Branded Food Database which draws on nutrition information panel and ingredient data. Total Diet Study data (from analytical surveys) are also used in chemical risk assessments.

The food classification system of the NNS is based on the food groups referred to in the food selection guide linked to the ADG. Food codes are then organised in hierarchical order with higher degrees of specificity, detailing the food, raw or cooked and with ingredients, producing a unique nutrient profile. Details of the classification system are provided in AUSNUT documents (FSANZ 2025a).

The construction of the AUSNUT database aligns with dietary guidelines that distinguishes raw/basic foods from those with added sugar, salt and fat. These

components - referred to in policy guidelines as 'risk nutrients' - have become a focus for food labelling. However, it is recognised that labels address individual foods, but dietary guidelines relate to food groups and dietary patterns (Australian Government 2020). The Preliminary Position Paper on the NIP Review refers to the policy guideline on food labelling, when it states consumers need to be able to identify foods that do and do not contribute to healthy dietary patterns (FSANZ 2025b), but distinguishing between foods still does not address food combinations seen in dietary patterns.

5.5.2 Distinguishing between food quality and risk nutrient composition

Addressing risk through the lens of healthy dietary patterns places further needs on food databases. While there are ongoing changes in food formulations, parameters for defining healthy foods and diets continue to evolve. For example, following the 2024 update of US-FDA's definition of 'healthy' for use on food labels, one study linking data on nutrient density and frequency of consumption with monetary cost of food (Hooker et al. 2025) found that most foods and beverages in the Food and Nutrient Database for Dietary Studies did not qualify as 'healthy'. Apparently the revised 'healthy' definition considered how foods would contribute to a healthy dietary pattern so only whole, raw fruits and vegetables automatically qualified. Despite the limitations of the databases and other methodological considerations, this analysis may suggest the overall food supply is of a poor-quality.

A practical approach would be to utilise nuanced approaches to food definitions and classifications. The challenge lies in identifying food and beverage products with the potential to negatively impact healthy dietary patterns. In one study, Popkin and colleagues used an approach combining HFSS criteria with UPF (a classification that includes the presence of additives) to identify less healthy foods (Popkin et al. 2024). Of note, this analysis utilised Neilsen IQ data linked with nutrition facts label data, exemplifying an area in which data from commercial sources could be utilised in an expanded risk management model.

The question remains on the place for processed food and how this might be addressed beyond risk nutrients. It also questions the value of relying entirely on reductionist risk-nutrient-based approaches to defining healthy dietary patterns. Additional recognition of the effects of foods as an entity would create a more robust approach to nutrition concerns (Jacobs and Tapsell 2007). For example, the Mediterranean diet is characterised by certain food groups (eg vegetables, nuts, olive oil), and while risk nutrients remain relevant, there is separate evidence supporting the foods themselves. It is not the case when the diet is reduced to risk nutrient profiles alone. Examining a dietary pattern in terms of foods first and risk nutrients second would encompass a much deeper evidence base.

This has implications for risk assessments involving novel foods as well as policy related strategies such as Health Star Rating. As 'risk nutrients' are chemicals of interest, their food sources need to be considered in the context of a healthy diet, not

just in individual foods. While NNS analyses would identify the major food sources of these nutrients, these foods could be distinguished in terms of their significance in health dietary patterns. Food databases would need to support analyses that address considerations of (healthy) food category as well as risk nutrients to serve the questions on effects on dietary patterns in problem formulation.

5.6 FSANZ Approaches to Dietary Exposure Assessment

National Nutrition Surveys are one of several resources available for dietary exposure assessment. FSANZ maintains an up-to-date publication, summarised here, on the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024). Dietary exposure assessments are part of its risk assessment processes, mainly in the assessment of Applications and Proposals. A set of principles guides the development of assessments and methodologies applied.

Features of the National Nutrition Surveys (NNS) used in FSANZ dietary exposure assessments (2011-12 NNPAS, 2012-1-2013 NATSINPAS, 2002 NZCNS, 2008/9 NZANS) are well documented. The Australian Bureau of Statistics (ABS) provides relevant publications of analyses from the NNPAS (for example consumption of food groups from the Australian Dietary Guidelines (NHMRC 2013) Additional Diet and Nutrition Surveys (DNS) are sometimes obtained or commissioned for specific purposes, for example for infants and young children, or assessment of intense sweeteners.

The limitations of the NNS dietary assessment methods are described in the FSANZ document, noting that care must be taken in using these data for assessing long term food consumption patterns. Reference is made to international best practice (FAO and WHO), and details are provided of thoughtful statistical adjustments. It is noted that the choice of approach is different for nutrients (except alcohol) and other types of food chemicals because the former are widely dispersed in foods. This represents another important distinction to make when comparing chemical risk assessment with nutrition risk assessment.

Statistical approaches including modelling usual intake from two- or more-day recalls, de-attenuation of correlations, and separation of within- and between-person variance are consistent with international best practice but cannot fully compensate for systematic misreporting or non-coverage of specific sub-populations. The evidence base shows that, even with multiple recalls and sophisticated modelling, usual intake estimation for episodically consumed foods and nutrients remains uncertain, especially where consumption probabilities are low or seasonally patterned (Conrad and Nothlings 2017; Illner et al. 2012; Naska et al. 2017). This is particularly relevant when FSANZ uses NNS to characterize high-percentile exposures (e.g. P90/P95) for both nutrients and chemicals, where tail estimates are sensitive to these methodological choices.

In the FSANZ document, the advantages to exposure assessment of individual dietary data provided through NNS are acknowledged, including analysis of foods and food groups that may be of interest for population health. However, these surveys are expensive, the analyses are time consuming, and the details on individual foods may be insufficient for risk assessment purposes. The age of the data, the limitations of the referent food composition tables, and the timeliness of data collection are further limitations.

The high operational cost and complexity of interviewer-administered 24-hour recalls, and associated coding are major drivers of infrequent survey cycles. International reviews highlight that traditional paper-based or interviewer-intensive surveys can cost substantially more than web-based or automated alternatives (van Rossum et al. 2022), and that this financial burden contributes directly to "data obsolescence", with national surveys often a decade apart (Ngo et al. 2009). For an agency such as FSANZ working in a fast-moving food system, this time lag means that exposure estimates based on NNS may not fully reflect current product portfolios, reformulation activities, or emerging categories such as plant-based analogues and novel beverages.

Other available forms of data identified include Food Balance Sheets (FAO), Apparent Consumption Data (ABS), Market share/uptake data (FAO and WHO) and consumer research data. Dietary exposure assessment is assisted with the FSANZ custom built computer application *HARVEST*. Thus, there is an array of data sources on which nutritional risk assessment draws and indeed may combine. For example, a 'market weighted assessment' uses data from both the NNS and market uptake information, but again it focuses on chemical exposure.

5.7 Implications for FSANZ Processes

The panel noted that FSANZ has several world class resources to address dietary exposure, and with capacity to pivot for additional questions. For example, the Total Diet Study (TDS) run by the surveillance team under the food safety unit provides a means of looking across the whole diet. A reductionist approach is used as the TDS is currently designed to look at individual chemicals, nutrient density or nutrient adequacy of the diet. As such, it captures the diet in terms of nutrient, not food combinations and does not address dietary patterns in relation to NCDs. The focus is on food formulations and composition, not how it may influence food choice and eating behaviour. Thus, it appears there is no current assessment of how a new food additive may change food consumption patterns, although manufacturer's product testing would consider palatability. In future it may be possible to question applicants on anticipated changes in consumption patterns. Another suggestion from the panel was to use the NNS to develop proxies for changes to dietary patterns, but this may require some external specialist resources. In the meantime, the TDS can still track changes over time.

The panel heard that the dietary modelling team is already working in the dietary patterns space but more around NNS analyses and health star ratings, and in building

food databases. However, there appears to be capacity to work with applications, considering intake predictions and modelling scenarios, and looking at potential displacement of foods by novel foods based on current consumption. This would take a shift in thinking to food categories rather than just nutrients, with scenarios that could be built from key risk questions developed in problem formulation. Behavioural insights from the social sciences would help here. The panel also noted that the annual consumer tracker managed by the economics and social science team is a valuable resource that could provide further insights into likely trends associated with applications.

The panel also noted there may be benefits in considering cumulative effects from a class of applications, and additional industry data may also be required on levels of food additives. The dietary modelling team appears confident they can deal with discretionary foods categories (proxies for UPF) as they are flagged in the database. Being able to connect applications with these foods is a significant capability. In the future, prospective modelling of dietary change could be done, possibly supplemented with generative AI to identify scenarios.

5.7 Conclusions

National Nutrition Surveys form an integral part of the principles and practices of dietary exposure assessment undertaken by FSANZ. A broader public health risk assessment framework would expand current use to identify food categories likely to be problematic in protecting healthy dietary patterns, with implications for applications relating to novel foods, and new processing technologies.

The limitations of NNS are well recognised, and timeliness is a major issue for examining the impacts of new products. Where products are analogues of traditional foods, impacts on nutrient adequacy, determined by comparative analysis, remains core business. Without evidence of the health benefit of the food or associated dietary pattern, there is a strong case for requiring post-market monitoring, with data supplied by industry. This is particularly the case for those foods likely to displace traditional foods.

Likewise, food databases need to be continually developed and able to deliver analyses on trends relating to both raw and prepared foods as well as commercial products. This will also enable various forms of data to be analysed, for various risk management purposes.

The panel noted that the FSANZ teams have strong capability to work in an integrated problem-oriented approach to public health risk management. This could now include food and dietary pattern issues in problem formulation across the board, particularly bringing together the nutrition team with social sciences, food safety and dietary modelling.

Thie approach implies a dual lens in NRA: one that considers "chemical-as-hazard" (e.g., contaminants, additives, residues) and another that considers "food-as-hazard or protection" within dietary patterns (e.g., the net effect of discretionary cereal-based foods on saturated fat, sodium, and added sugars). NNS are uniquely placed to support the second lens by identifying which foods carry the largest share of both beneficial and harmful nutrients in real-world diets and how these change as new technologies and processing techniques are adopted.

In summary, the main application of dietary exposure assessment by FSANZ has been chemical risk assessment, and public health impacts of changes to nutrient delivery. However, dietary exposure assessment can be used to assess changes in food consumption patterns to 'evaluate the public health impact of food standards over time' which suggests current approaches could be broadened. While NNS data cannot predict how consumers will change their eating patterns, there may be several locations for dietary assessment in a risk governance framework.

References for Chapter 5

ABS (Australian Bureau of Statistics) (2025) Food and nutrients, ABS Website, Canberra, https://www.abs.gov.au/statistics/health/food-and-nutrition/food-and-nutrients/latest-release#selected-micronutrients-and-caffeine

Australian Government (2020) Policy guideline on food labelling to support consumers to make informed healthy food choices, Australian Government, Canberra. https://www.foodregulation.gov.au/sites/default/files/2023-09/policy-guideline-on-food-labelling-to-support-consumers-to-make-informed-healthy-choices.pdf

Boushey CJ, Spoden M, Zhu FM, Delp EJ and Kerr DA (2017) New mobile methods for dietary assessment: review of image-assisted and image-based dietary assessment methods. *Proceedings of the Nutrition Society*, 76(3):283-294, doi.org/10.1017/s0029665116002913.

Conrad J and Nöthlings U (2017) Innovative approaches to estimate individual usual dietary intake in large-scale epidemiological studies, *Proceedings of the Nutrition Society,* 76(3), 213–219, doi:10.1017/S0029665116003025.

Harmer I, Craddock JC and Charlton KE (2024) How do plant-based milks compare to cow's milk nutritionally? An audit of the plant-based milk products available in Australia. *Nutrition & Dietetics*, 82(1):76-85, doi:10.1111/1747-0080.12906.

FSANZ (2024a) Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes, Food Standards Australia New Zealand, Canberra, https://www.foodstandards.gov.au/publications/principles-and-practices-of-dietary-exposure-assessment. Accessed 20 April 2026.

FSANZ (2024b) Principles and practices of dietary exposure assessment for food regulatory purposes, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/publications/principles-and-practices-of-dietary-exposure-assessment

FSANZ (2025a) Australian Food and Nutrient Database (AUSNUT) 2023 - Classifications. Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/science-data/food-nutrient-databases/ausnut/classification%20systems

FSANZ (2025b) Preliminary Position Paper on the Nutrient Information Panel review, Food Standards Australia New Zealand, Canberra, https://www.foodstandards.gov.au/sites/default/files/2025-11/Preliminary%20Position%20Paper%20-%20NIP%20Review%20-%20Nov2025.pdf

Hooker K, Sanjeevi N and Monsivais P (2025) An Updated Definition of "Healthy" Foods in the United States: How Do They Measure in Nutrient Density, Cost, and Frequency of Consumption? *Current Developments in Nutrition,* 9(10), do:10.1016/j.cdnut.2025.107545.

Illner AK, Freisling H, Boeing H. Huybrechts I, Crispim SP and Slimani N (2012) Review and evaluation of innovative technologies for measuring diet in nutritional epidemiology, *International Journal of Epidemiology*, 41(4):1187–1203, doi:10.1093/ije/dys105.

Jacobs DR and Tapsell LC (2007) Food, not nutrients, is the fundamental unit in nutrition. *Nutrition Reviews*, 65(10):439-50, doi:10.1111/j.1753-4887.2007.tb00269.x.

Jiménez MDCF and López-Moreno M (2025) Ultra-processed Plant Foods: Are They Worse than their Unprocessed Animal-Based Counterparts?, *Curr*ent *Nutrition Reports, 14, 115*, doi:10.1007/s13668-025-00704-6.

Johnson A, Stevenson J, Pettit J, Jasthi B, Byhre T and Harnack L (2025) Assessing the Nutrient Content of Plant-Based Milk Alternative Products Available in the United States, *Journal of the Academy of Nutrition and Dietetics,* 125(4):515-527.e8, doi:10.1016/j.jand.2024.06.003.

Naska A, Lagiou A and Lagiou P (2017) Dietary assessment methods in epidemiological research: current state of the art and future prospects. *F1000Research*, 6(F1000 Faculty Rev):926, doi:10.12688/f1000research.10703.1.

Ngo J, Engelen A, Molag M, Roesle J, García-Segovia P and Serra-Majem L (2009) A review of the use of information and communication technologies for dietary assessment, *British Journal of Nutrition*, 101(S2):S102–S112, doi:10.1017/S0007114509990638.

NHMRC (2013) Australian Dietary Guidelines. National Health and Medical Research Council, Canberra. https://www.health.gov.au/sites/default/files/australian-dietary-guidelines.pdf

Nowson GK, Fallaize R and Earl KE (2025) Exploring the Nutritional Profile and Cost of Plant-Based Milk Alternatives Compared with Dairy Milk in the UK with Consideration of Environmental Impact Data, *Current Developments in Nutrition,* 9(6), 107436, doi:10.1016/j.cdnut.2025.107436.

Popkin BM, Miles DR, Taillie LS and Dunford KE (2024) A policy approach to identifying food and beverage products that are ultra-processed and high in added salt, sugar and saturated fat in the United States: a cross-sectional analysis of packaged foods, *The Lancet Regional Health- Americas,* 32,100713, doi:10.1016/j.lana.2024.100713.

Rossum CV, Borg St, Nawijn E, Oliveira A, Carvalho C and Ocke M (2022) Literature review on methodologies and tools for national dietary surveys; results of ERA EU-menu-project, *EFSA Supporting Publications,* 19(12):EN-7725, doi:10.2903/sp.efsa.2022.EN-7725.

PART III: BUILDING A BLUEPRINT FOR PURPOSIVE FUTURE NUTRITION RISK ASSESSMENT

CHAPTER 6: FROM RISK ANALYSIS TO RISK GOVERNANCE: EVOLVING FSANZ NUTRITION RISK ASSESSMENT FOR DECISION-CENTRED AND ADAPTIVE POLICYMAKING

6.1 Summary

The panel considers that FSANZ has a strong and well-established foundation in risk analysis, and that this foundation remains fully relevant. At the same time, the nature of contemporary nutrition-related public health challenges suggests that FSANZ would benefit from making its approach more explicitly **decision-centered, adaptive, and governance-oriented**. This chapter therefore proposes an evolution in emphasis: from a model in which nutrition risk assessment is understood primarily as a technical component within a broader regulatory workflow, to a model in which it is embedded more explicitly within a broader system of **risk governance**.

This proposed evolution is strongly supported by international guidance and scholarship. Across these sources, several themes recur consistently: the importance of governance-oriented handling of complex and systemic risks; the centrality of structured problem formulation; the need for explicit treatment of uncertainty and variability; the value of continuous two-way communication and stakeholder engagement; and the importance of monitoring, evaluation, and learning as integral parts of the risk-handling cycle rather than downstream add-ons (IRGC 2017; NRC 2009; Renn and Klinke 2013).

The panel emphasizes that this is not a proposal to replace Codex risk analysis or to weaken the distinction between risk assessment and risk management. On the contrary, the Codex framework remains the essential foundation. Codex already recognizes several principles that are fully compatible with a governance perspective, including the need for transparency, functional separation, iterative interaction, attention to uncertainty, and continuing review of decisions considering new information (FAO and WHO 2003 FAO and WHO 2007). FSANZ's own materials similarly reflect these principles (FSANZ 2025). The issue, therefore, is not one of rupture, but one of development: making more explicit, more coherent, and more operational those features that are already present in part within current practice.

The case for this development is particularly strong in the nutrition domain. Diet-related NCDs do not generally arise from a single hazard–exposure pathway. They emerge from dietary patterns and food environments shaped by a wide range of interacting determinants, including availability, affordability, composition, marketing, placement, processing, retail settings, social norms, and inequality (Hayashi and Takemi 2015; Hyseni et al. 2017; Løvhaug et al. 2022; Moodie et al. 2021; Nugent

2004; Weimann et al. 2021). Such problems are not well represented by a narrowly linear sequence of "assessment–management–communication" if that sequence is treated as the whole logic of decision-making. What is needed is a framework that preserves scientific rigor while also making the decision context, the policy choices, the uncertainties, the trade-offs, and the feedback loops more explicit.

A risk governance framing provides that broader architecture. It situates risk assessment within a continuing process of issue framing, appraisal, evaluation, management, communication, monitoring, and review (IRGC 2017). In this model, problem formulation becomes the front end of the assessment; evidence systems and risk communication operate continuously rather than sequentially; the interface between assessors and managers becomes more structured and purposeful; and monitoring and learning become explicit parts of the process rather than optional later stages.

The panel therefore proposes that FSANZ retain the Codex four-stage risk assessment process but embed it within a broader model of nutrition risk governance. Many of the required capabilities already exist within FSANZ. The principal need is for a more explicit and integrated articulation of how these capabilities work together to support decision-centered and adaptive policymaking.

6.2 Introduction

6.2.1 Purpose of this chapter

This chapter sets out the conceptual basis for evolving FSANZ's Nutrition Risk Assessment (NRA) into a more explicit system of nutrition risk governance. Its purpose is not to challenge the scientific validity of current approaches, but to explain why the complexity of modern nutrition-related public health problems calls for a broader organizing framework.

The chapter addresses three questions:

1. Why is a risk governance perspective relevant to nutrition risk assessment?
2. How does such a perspective relate to, and remain consistent with, Codex and FSANZ's existing risk analysis framework?
3. What would a governance-oriented NRA look like in practice?

This chapter should be read together with the case studies in Part IV of this report, which illustrate how the proposed framework may operate in concrete settings.

6.2.2 The starting point: a strong existing platform

The panel notes at the outset that FSANZ already operates within a robust and internationally respected risk analysis tradition. FSANZ's statutory purpose is to protect public health and consumer safety through the development and administration of

food standards and associated regulatory processes (FSANZ 2025). Its current practice is grounded in scientific assessment, transparency, documentation, and consultation, and benchmarks well with international peers (FSANZ 2025).

This matters because the proposal set out in this chapter is not built on a claim of institutional weakness. Rather, it proceeds from the view that FSANZ already has many of the elements needed for a more explicit governance model. What is now required is a clearer organizing structure that reflects the types of nutrition-related policy questions FSANZ increasingly faces.

6.2.3 Why nutrition creates a special challenge

Many classic food safety questions fit comfortably within a conventional risk analysis and risk assessment structure. The core task may be to assess whether a contaminant, additive, or pathogen presents a risk under specified conditions of exposure, and then to support a management decision. Nutrition-related risks are often different. The issue is frequently not whether one substance exceeds one threshold, but how patterns of diet and food environments contribute over time to chronic disease risk.

This creates a different decision context. The regulator may need to consider not only biological plausibility and exposure, but also behavioral response, substitution effects, implementation feasibility, equity impacts, consumer understanding, and the cumulative or interacting effects of multiple policy measures (Hyseni et al. 2017; Watkins 2019; Blanchard et al. 2024a; Buse et al. 2020; Alonge et al. 2024). Such questions cannot be answered well by technical characterization alone. They require a framework that links assessment more explicitly to decision needs and to the realities of implementation and review.

6.3 Conceptual foundation: continuity with Codex, extension through governance

6.3.1 The enduring value of the Red Book tradition

The National Research Council's *Red Book* provided the foundational logic for modern risk analysis by distinguishing clearly between risk assessment and risk management and by emphasizing scientific independence, transparency, and structured analysis (NRC 1983). This architecture has had lasting value and remains essential in food regulation. It helps protect the integrity of scientific judgement and makes explicit distinction between evidence and policy choice.

Codex adopted and operationalized this logic through its working principles for risk analysis (FAO and WHO 2003; FAO and WHO 2007). The Codex framework remains the key international reference point for food regulatory authorities, including FSANZ, and continues to provide a robust procedural and conceptual basis for standards development and related decision-making (FAO and WHO 2003; FAO and WHO 2007; Hoffmann 2010).

6.3.2 The significance of the Silver Book

The *Silver Book* did not displace the *Red Book*; it updated it. Its central contribution was to show that risk assessment is most useful when it is explicitly designed in relation to the decision context in which it will be used (NRC, 2009). It therefore elevated **problem formulation and scoping** as a formal and necessary stage of the process. This stage is not simply a planning exercise. It is where the purpose, scope, boundaries, options, and constraints of the assessment are clarified, so that the assessment becomes fit for purpose rather than merely comprehensive in the abstract (NRC 2009; Solomon et al. 2016).

The *Silver Book* also brought much stronger emphasis to uncertainty and variability, not as peripheral technical matters, but as central determinants of decision utility (NRC 2009). This shift is highly relevant to nutrition-related assessments, where evidence is often heterogeneous, causal pathways are long and indirect, and decisions may need to be made despite incomplete knowledge.

6.3.3 What risk governance adds

Risk governance builds on this progression by recognizing that many modern public health risks are characterized not only by technical uncertainty, but also by complexity, ambiguity, distributed authority, and contested values (IRGC 2017; Renn and Klinke 2013). It therefore frames risk assessment as one component of a broader and more adaptive governance cycle that includes issue framing, appraisal, evaluation, management, communication, monitoring, and review (IRGC 2017).

This is especially relevant to nutrition. Decisions about diet-related risks are rarely confined to a single hazard or a single exposure route. They often involve trade-offs between health objectives, practicality, commercial impacts, consumer expectations, and equity concerns. A governance approach does not eliminate these tensions. It provides a clearer and more transparent way of handling them.

6.4 Why risk governance is relevant for Nutrition Risk Assessment

6.4.1 Nutrition risks are shaped by systems

A central insight of the literature reviewed by the panel is that nutrition risks are produced through systems. Food environments in food systems influence dietary choices through affordability, availability, convenience, marketing, placement, retail settings, reformulation, and social norms (Hayashi and Takemi, 2015; Hyseni et al. 2017; Løvhaug et al. 2022; Moodie et al. 2021). These determinants can reinforce inequalities and can interact in ways that are not well captured by a narrow technical model.

This systems character matters because it changes the type of question a regulator must answer. The issue is often not simply whether a given exposure is harmful, but what combination of interventions is likely to shift population diets in a healthier direction, for whom, over what timeframe, and with what trade-offs (Blanchard et al. 2024a; Hyseni et al. 2017; Watkins 2019).

6.4.2 Why a linear model can become too narrow

The classic formulation of risk analysis as a sequence of risk assessment, risk management, and risk communication remains valuable. The difficulty arises when that sequence is interpreted too rigidly. In practice, effective nutrition policy may require earlier dialogue about what decision is being supported, broader integration of different evidence types, and continuing engagement after a decision has been made.

For example, a technically valid estimate of the effect of one intervention may still be insufficient if the likely outcome depends heavily on substitution effects, industry response, implementation fidelity, or differential impact across socioeconomic groups (Blanchard et al. 2024b; Buse et al. 2020; Hyseni et al. 2017; Jain et al. 2020; Løvhaug et al. 2022). A governance model does not replace technical analysis in such cases; it makes explicit the broader set of considerations required for technically sound analysis to be useful in practice.

6.4.3 Why these matters for FSANZ

For FSANZ, the added value of a governance approach lies in its capacity to connect scientific assessment more directly to actual policy choices. It supports a clearer understanding of:

- what problem is being addressed,
- which populations are most affected,
- which options are realistically available,
- how uncertainty should influence proportionality,
- what should be monitored after implementation,
- and how the assessment should be revisited as new evidence emerges.

This is particularly important where nutrition policy seeks to influence long-term population outcomes rather than resolve immediate and clearly bounded food safety concerns.

6.5 Core features of a governance-oriented Nutrition Risk Assessment

Figure 6.1 presents a risk governance–oriented framework for nutrition risk assessment, highlighting key components and their interconnections. Italic red text

indicates elements that are newly introduced or were previously less explicit in the current FSANZ framework.

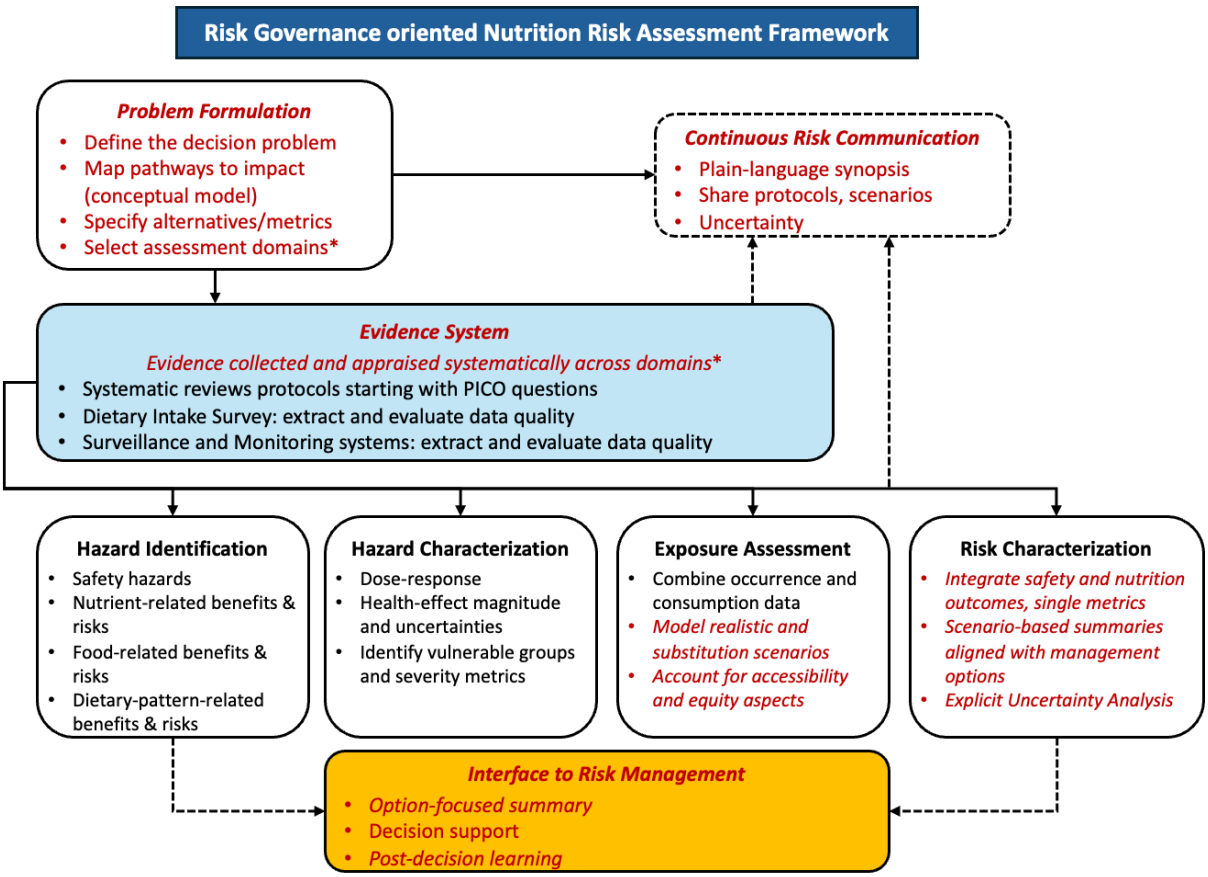


Figure 6.1: **Risk Governance–Oriented Nutrition Risk Assessment Framework.** *Italic red text highlights new or previously less explicit elements in the current FSANZ framework.*

6.5.1 Problem formulation as a formal front-end stage

The panel considers that the most important practical development in FSANZ's NRA framework would be the strengthening of **problem formulation**. In a governance-oriented model, this becomes a formal stage at the beginning of the process, not an implicit activity dispersed across later steps.

Problem formulation should clarify:

- the public health problem,
- the decision to be made,
- the management options that are plausibly available,
- the outcomes of interest,
- the populations likely to be affected,
- and the scope and depth of analysis required (NRC 2009; Solomon et al. 2016).

This stage is important for efficiency as well as for quality. It helps ensure that analytical effort is directed toward the questions most relevant to decision-making rather than toward an undifferentiated accumulation of evidence.

6.5.2 Decision-ready and contingent analysis

The next implication of a governance model is that assessments should be designed to produce **decision-ready outputs**. This means going beyond characterizing "what the risk is" and, where appropriate, assessing how risk or benefit may change under alternative interventions, alone or in combination (Blanchard et al. 2024a; Buse et al. 2020; Hyseni et al. 2017; Watkins 2019).

This is especially relevant in nutrition policy, where policy mixes are often more effective than isolated instruments and where the choice may be between several imperfect options rather than between action and inaction (Blanchard et al. 2024a; Watkins 2019). The role of assessment is therefore not only to describe, but also to compare.

6.5.3 Explicit treatment of uncertainty and variability

A governance-oriented NRA requires uncertainty and variability to be made explicit and usable. Codex and FSANZ already acknowledge this principle (FAO and WHO 2003; FSANZ 2025). The panel proposes that it be brought more centrally into the design and communication of assessments.

This means that where feasible, assessments should:

- describe data limitations and default assumptions,
- distinguish variability from uncertainty,
- present ranges and sensitivity analyses,
- and explain clearly how robust the conclusions are (NRC 2009; Ozkaynak et al. 2008; Thompson 2002; Zwietering 2015).

The purpose is not to eliminate uncertainty, which is rarely possible, but to support proportionate and transparent decisions under uncertainty.

6.5.4 Integrated evidence systems

The panel also considers that FSANZ would benefit from a more explicit concept of **evidence systems** in nutrition risk assessment. In many nutrition policy questions, relevant evidence extends beyond exposure-response relationships to include behavioral, economic, implementation, and equity evidence (Alonge et al. 2024; Blanchard et al. 2024b; Hyseni et al. 2017; Jain et al. 2020).

Such evidence should not be treated as supplementary or external to the assessment if it materially affects the real-world meaning of the decision. Rather, the assessment

process should specify which forms of evidence are needed to answer the decision question and how they will be integrated.

6.5.5 Continuous communication and participation

Risk governance also implies a broader understanding of communication. Communication is not simply the final explanation of a completed assessment. It is a continuing process through which assessors, managers, stakeholders, and interested parties understand the issue, contribute relevant information, and receive explanations of how decisions were reached (FAO and WHO 2003; IRGC, 2017).

This includes stakeholder engagement, which should be structured and purposeful. In nutrition, stakeholder dialogue can improve legitimacy, help identify practical barriers, surface concerns early, and support implementation (Hanssen et al. 2018; Papadopoulos et al. 2012).

6.5.6 Monitoring, review, and learning

Finally, a governance-oriented NRA embeds monitoring and learning into the framework from the start. This means asking, at the point of assessment, what indicators would be needed to judge whether the policy is working, what baseline data are required, what unintended consequences should be watched for, and when review should occur (FSANZ 2025; IRGC 2017; Ngqangashe et al. 2022; Swinburn et al. 2013).

The panel regards this as especially important in nutrition, where effects may emerge gradually and where policies may have different consequences across populations or over time.

6.6 Uncertainty, variability, and the assessor–manager interface

6.6.1 Why this interface deserves more attention

One of the clearest lessons from the literature is that the quality of decision-making depends not only on the quality of scientific analysis, but also on the quality of the interface between those who produce it and those who must act on it (NRC 2009; Thompson 2002; Zwietering 2015).

This is particularly evident in relation to uncertainty. Scientific teams may be able to characterize variability and uncertainty technically, but unless that information is translated into decision-relevant terms, its practical value remains limited.

6.6.2 Distinguishing variability from uncertainty

The distinction is important. Variability refers to real differences across people, places, or circumstances. Uncertainty refers to incomplete knowledge about those realities (Ozkaynak et al. 2008; Thompson 2002). This distinction matters for policy because it shapes the response. Variability may imply subgroup targeting or equity-sensitive design. Uncertainty may imply staged implementation, additional evidence generation, or closer monitoring.

6.6.3 Moving beyond point estimates

The panel therefore considers that, where feasible and justified by the problem, NRA should move beyond narrow point estimates and provide more information about the range and distribution of plausible outcomes (NRC 2009; Ozkaynak et al. 2008; Zwietering 2015). This may include ranges, sensitivity analysis, distributions, or scenario-based outputs. The key point is not methodological sophistication for its own sake, but better support for proportionate decisions.

6.7 Monitoring, evaluation, and adaptive governance

6.7.1 Monitoring as part of governance, not only implementation

The panel proposes that monitoring and evaluation be treated as an explicit governance requirement rather than a downstream administrative task. The IRGC framework is clear that review and monitoring are part of the cycle of governance itself (IRGC 2017). The literature on food policy similarly suggests that comprehensive monitoring is often a necessary condition for meaningful policy impact (Ngqangashe et al. 2022a; Swinburn et al. 2013).

6.7.2 What should be monitored

Depending on the case, monitoring may include:

- uptake,
- changes in exposure,
- shifts in diet quality,
- substitution and compensation effects,
- equity impacts,
- implementation fidelity,
- and unintended consequences (Ngqangashe et al. 2022b; Swinburn et al. 2013).

The appropriate indicators will vary by intervention, but the principle is constant: they should be planned from the outset.

6.7.3 Why this strengthens decision-making

Monitoring strengthens decision-making in two ways. It improves future learning by generating evidence on what worked and under what conditions. It also improves current decision-making by allowing a policy to be designed as adaptive rather than final, which is especially valuable where uncertainty remains high.

6.8 A proposed framework for Nutrition Risk Assessment by FSANZ

6.8.1 The core policy problem

The panel identified the following overarching question:

How do risk assessment and allied approaches used by regulatory authorities identify and characterize the chronic disease risks and benefits associated with changing dietary patterns, and inform the selection of appropriate risk management and mitigation strategies (Buse et al. 2020; Ozkaynak et al. 2008)?

This problem differs materially from classic questions of nutritional adequacy or direct toxicological safety. It involves patterns, long-term outcomes, intervention mixes, and implementation conditions.

6.8.2 The proposed framework

The panel proposes that FSANZ retain the Codex four-stage risk assessment process: hazard identification, hazard characterization, exposure assessment, and risk characterization, but embed it within a broader framework that includes:

- Problem Formulation
- Evidence Systems
- Continuous Risk Communication
- Structured Interface with Risk Management
- Options Appraisal
- Implementation, Monitoring, and Review

In this model:

- Problem formulation defines the context, objectives, options, outcomes, and scope.
- Risk assessment proceeds through the established Codex stages.
- Evidence systems support structured integration of relevant evidence and uncertainty.
- Risk communication operates throughout the cycle.
- The interface with management ensures that outputs are decision ready.

- Monitoring and review create a feedback loop for refinement.

6.8.3 Relationship to current FSANZ capabilities

The panel notes that many components of this framework already exist within FSANZ, although not always explicitly connected in one overarching model. This suggests that adoption is feasible in principle. The principal challenge is not conceptual feasibility, but organizational and procedural integration.

6.8.4 Practical starting points

As a practical starting point, the panel sees particular value in strengthening the **Problem Formulation** stage and in clarifying workflow, decision points, and cross-team collaboration (FSANZ 2025; NRC 2009; Solomon et al. 2016). This would create a stronger front end for the entire process and would improve the relevance of subsequent evidence collection and analysis.

6.9 Organizational and implementation implications

6.9.1 A shift toward more problem-oriented working

The panel recognizes that implementation of the proposed framework may require some shift from a primarily team-siloed operating model toward a more problem-oriented, cross-disciplinary mode of work, supported by executive leadership and clear process ownership (Ngqangashe et al. 2022b;).

6.9.2 Stakeholder engagement

Stakeholder engagement should be treated as deliberate two-way dialogue across the full cycle, including explanation of the rationale for decisions after they are made (IRGC 2017; Papadopoulos et al. 2012).

6.9.3 Equity

Equity should be operationalized as an explicit criterion rather than assumed as a co-benefit. There is strong evidence of inequalities in food environments and of insufficient use of distributional analysis in policy evaluation (Blanchard et al. 2024b; Jain et al. 2020; Løvhaug et al. 2022).

6.9.4 Monitoring and evaluation planning

Monitoring and evaluation should be planned from the beginning, with measurable indicators and baseline data linked to intended outcomes (FSANZ 2025; Ngqangashe et al. 2022; Swinburn et al. 2013).

6.10 Concluding perspective

The panel's proposal is best understood as an evolution in emphasis, structure, and explicitness. FSANZ already operates from a strong risk analysis foundation and already incorporates many governance-compatible features. The next step is to articulate these more coherently in a framework that is better aligned with the complexity of modern nutrition policy.

A governance-oriented NRA would preserve scientific integrity, maintain the discipline of Codex risk analysis, and retain functional separation where needed. At the same time, it would strengthen decision relevance, transparency, adaptability, and public legitimacy. In a policy landscape where nutrition risks increasingly arise from systems rather than isolated agents, such an evolution is both timely and well supported by the international literature (FAO and WHO 2003; IGRC 2017; NRC 2009).

References for Chapter 6

Alonge O, Homsi M, Rizvi M S, Malykh R, Geffert K, Kasymova N, Tilenbaeva N, Isakova L, Kushubakova M, Mavlyanova D, Mamyrbaeva T, Duishenkulova M, Pinedo A, Andreeva O and Wickramasinghe K (2024) Implementation of school nutrition policies to address noncommunicable diseases in Uzbekistan and Kyrgyzstan, *Global Health: Science and Practice*, 12(4):e2300442, doi:10.9745/GHSP-D-23-00442.

Blanchard L, Ray S, Law C, Vega-Salas MJ, Bidonde J, Bridge G, Egan M, Petticrew M, Rutter H and Knai C (2024a) The effectiveness, cost-effectiveness and policy processes of regulatory, voluntary and partnership policies to improve food environments: An evidence synthesis, *Public Health Research*, 12(8), doi:10.3310/JYWP4049.

Blanchard L, Ray S, Law C, Vega-Salas MJ, Rutter H, Egan M, Petticrew M, Potvin Kent M, Bennett C, Lucas PJ and Knai C (2024b) Inequalities in research on food environment policies: An evidence map of global evidence from 2010–2020. *Advances in Nutrition*, 15(11):100306, doi:10.1016/j.advnut.2024.100306.

Buse K, Aftab W, Akhter S, Phuong LB, Chemli H, Dahal M, Feroz A, Hofiani S, Pradhan NA, Anwar I, Skhiri HA, El Ati J, Giang KB, Puri M, Noormal B, Rabbani F and Hawkes S (2020) The state of diet-related NCD policies in Afghanistan, Bangladesh, Nepal, Pakistan, Tunisia and Vietnam: A comparative assessment that introduces a "policy cube" approach, *Health Policy and Planning*, 35(5):503–521, doi:10.1093/heapol/czz175.

FAO and WHO (2003) Working principles for risk analysis for application in the framework of the Codex Alimentarius, Food and Agriculture Organisation and World Health Organisation. https://www.fao.org/4/y4800e/y4800e0o.htm

FAO and WHO (2007) Working principles for risk analysis for food safety for application by governments, Food and Agriculture Organisation and World Health Organisation. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B62-2007%252FCXG_062e.pdf

FSANZ (2025) Guidance Document for Nutrition Risk Assessment [Internal Use Only], July 2025.

Hanssen L, Devilee J, Hermans M, van Zijverden M and van Asselt M (2018) The use of risk governance principles in practice: Lessons from a Dutch public institute for risk research and assessment*, European Journal of Risk Regulation*, 9(4):632–640. doi:10.1017/err.2018.64.

Hayashi F and Takemi Y (2015) Why is creating a healthy food environment so crucial to making improvements in diet-related NCDs?, *Journal of Nutritional Science and Vitaminology,* 61(Supplement): S36–S38, doi:10.3177/jnsv.61.S36.

Hoffmann S (2010) Ensuring food safety around the globe: The many roles of risk analysis from risk ranking to microbial risk assessment, *Risk Analysis*, 30(5):711–714, doi:10.1111/j.1539-6924.2010.01437.x.

Hyseni L, Atkinson M, Bromley H, Orton L, Lloyd-Williams F, McGill R and Capewell S (2017) The effects of policy actions to improve population dietary patterns and prevent diet-related non-communicable diseases: Scoping review, *European Journal of Clinical Nutrition*, 71(6):694–711, doi:10.1038/ejcn.2016.234.

IRGC (2017) Introduction to the IRGC risk governance framework: Revised version, International Risk Governance Center. https://irgc.org/wp-content/uploads/2018/09/IRGC.-2017.-An-introduction-to-the-IRGC-Risk-Governance-Framework.-Revised-version..pdf

Jain V, Crosby L, Baker P and Chalkidou K (2020) Distributional equity as a consideration in economic and modelling evaluations of health taxes: A systematic review, *Health Policy*, 124(9):919–931, doi:10.1016/j.healthpol.2020.05.022.

Løvhaug AL, Granheim SI, Djojosoeparto SK, Harrington JM, Kamphuis CBM, Poelman MP, Roos G, Sawyer A, Stronks K, Torheim LE, Twohig C, Vandevijvere S, van Lenthe FJ and Terragni L (2022) The potential of food environment policies to reduce socioeconomic inequalities in diets and to improve healthy diets among lower socioeconomic groups: An umbrella review, *BMC Public Health*, 22(433), doi:10.1186/s12889-022-12827-4.

Moodie R, Bennett E, Kwong EJL, Santos TM, Pratiwi L, Williams J and Baker P (2021) Ultra-processed profits: The political economy of countering the global spread of ultra-processed foods, *International Journal of Health Policy and Management*, 10(12):968–982, doi:10.34172/ijhpm.2021.45.

NRC (National Research Council) (1983), Risk assessment in the federal government: Managing the process, National Research Council, *National Academies Press,* Washington, doi:10.17226/366.

NRC (2009) Science and decisions: Advancing risk assessment, National Research Council, *National Academies Press*, Washington, doi:10.17226/12209.

Ngqangashe Y, Goldman S, Schram A and Friel S (2022a) A narrative review of regulatory governance factors that shape food and nutrition policies*, Nutrition Reviews*, 80(2):200–214, doi:10.1093/nutrit/nuab023.

Ngqangashe Y, Friel and Schram A (2022a) The regulatory governance conditions that lead to food policies achieving improvements in population nutrition outcomes: A qualitative comparative analysis, *Public Health Nutrition*, 25(5):1395–1405, doi:10.1017/S1368980021004730.

Nugent R (2004) Food and agriculture policy: Issues related to prevention of noncommunicable diseases, *Food and Nutrition Bulletin*, 25(2):200–207, doi:10.1177/156482650402500214.

Özkaynak H, Frey HC and Hubbell B (2008) Characterizing variability and uncertainty in exposure assessments improves links to environmental decision-making, *EM (Pittsburgh Pa)*, 58(7):18–22.

Papadopoulos A, Sargeant JM, Majowicz SE, Sheldrick B, McKeen C, Wilson J and Dewey CE (2012) Enhancing public trust in the food safety regulatory system, *Health Policy*, 107(1):98–103, doi:10.1016/j.healthpol.2012.05.010.

Renn O and Klinke A (2013) A framework of adaptive risk governance for urban planning, *Sustainability*, 5(5):2036–2059, doi:10.3390/su5052036.

Solomon KR, Wilks MF, Bachman AN, Boobis, A, Moretto A, Pastoor TP, Phillips R and Embry MR (2016) Problem formulation for risk assessment of combined exposures to chemicals and other stressors in humans, *Critical Reviews in Toxicology*, 46(10):835–844, doi:10.1080/10408444.2016.1211617.

Swinburn B, Vandevijvere S, Kraak V, Sacks G, Snowdon W, Hawkes C, Barquera S, Friel S, Kelly B, Kumanyika S, L'Abbé, M, Lee A, Lobstein T, Ma J, Macmullan J, Mohan S, Monteiro C, Neal B, Rayner M, Sanders D, Walker C and INFORMAS (2013) Monitoring and benchmarking government policies and actions to improve the healthiness of food environments: A proposed Government Healthy Food Environment Policy Index, *Obesity Reviews*, 14(Suppl. 1):24–37, doi:10.1111/obr.12073.

Thompson KM (2002) Variability and uncertainty meet risk management and risk communication, *Risk Analysis*, 22(3):647–654, doi:10.1111/0272-4332.00044.

Watkins D (2019) Policy options for tackling diet-related noncommunicable diseases, *Bulletin of the World Health Organization*, 97(7):442–442A, doi:10.2471/BLT.19.236356.

Weimann A, Shung-King M, McCreedy N, Tatah L, Mapa-Tassou C, Muzenda T, Govia I, Were V and Oni T (2021) Intersectoral action for addressing NCDs through the food environment: An analysis of NCD framing in global policies and its relevance for the African contextm *International Journal of Environmental Research and Public Health*, 18(21):11246, doi:10.3390/ijerph182111246.

Zwietering MH (2015) Risk assessment and risk management for safe foods: Assessment needs inclusion of variability and uncertainty, management needs discrete decisions, *International Journal of Food Microbiology*, 213:118–123, doi:10.1016/j.ijfoodmicro.2015.03.032.

RECOMMENDATIONS OF THE FSANZ NUTRITION RISK ASSESSMENT REVIEW PANEL

The panel found the FSANZ internal guidance on nutrition risk assessment, most recently updated in 2025, to be a technically strong and internally coherent document that ensures methodological rigor and transparency in evidence review and synthesis. It aligns well with Codex's classical four-step framework for risk assessment (hazard identification, hazard characterization, exposure assessment, and risk characterization) and provides solid operational detail for FSANZ assessors.

The panel characterized these current approaches and processes as constituting a robust procedural guide for evidence appraisal within an assessment-oriented paradigm. The panel also concludes that the current approaches of FSANZ to nutrition risk assessment are broadly comparable with and equivalent to the approaches used by those other national risk assessment organizations which the panel considered to be FSANZ's peers, in terms of their development, sophistication, agility, and openness to consider developments in scientific knowledge relating to food and nutrition.

The current approaches of FSANZ and its international comparators provide a sound basis for the assessment of nutrients and novel food ingredients, but may be less well suited to assessments of whole foods or dietary patterns. The panel is proposing a transition to a more decision-led, problem-formulation-driven, and context-integrated approach set out in Chapter 6. This acknowledges the inherent complexity of food systems and the need simultaneously to address different hazards and endpoints, including those that are nutritional, toxicological, epidemiological, behavioral, or developmental.

Within the approach that the panel proposes, the problem formulation step is key. This step should aim to identify all relevant questions, acknowledging that not may be addressed by an initial risk assessment. Those questions may, however, inform hypotheses that can be tested as further knowledge is gained and data are collected, for example through post-market monitoring. Following problem formulation, the subsequent stages in risk assessment then retain the normative four-step approach while facilitating broader consideration of public health impact.

Like FSANZ, several of its international comparators have been incrementally developing their approaches to nutrition risk assessment over the past decade or two, having long recognised the need to address components of foods that are associated with increased risk of chronic disease, and the role that food and diet can play in either exacerbating or reducing chronic disease. In framing its recommendations, the panel has therefore also considered whether the enhancements to current processes that the panel recommends would in the real-world be best developed by FSANZ alone, or collaboratively with other, like-minded national food regulatory organizations.

To support their practical implementation, the panel has categorised its proposals using a maturity model approach into:

- **Recommendations that are ready to implement:** recommendations that could be implemented by FSANZ within its current legislative and policy environment. Within this category the panel has sought to differentiate between those process improvements that might be implemented at low or no cost and within current capabilities, and those which would be resource dependent.
- **Future opportunities for international coordination:** recommendations that could be explored with like-minded national regulators, with FSANZ taking the role of convenor and thought leader.
- **Longer term opportunities in the development of policy and legislation:** recommendations that would require changes to resources or the legislative and policy environment with, as appropriate, suggestions of how these might be surfaced and advocated by FSANZ.

Recommendations that are ready to implement

Process improvements that might be implemented at low or no cost and within current capabilities

Context setting and problem formulation

1. Set the context for problem formulation.

The panel advocates for an approach in which FSANZ clearly articulates the regulatory and wider context of the issue under discussion. When dealing with major, novel or contentious issues, there would be early engagement with stakeholders and perspective gathering to inform problem formulation by FSANZ. This approach, which is distinct from and in addition to the statutory consultation process, would aim to socialise the issues involved and help stakeholders to understand the context and framing of the issue, which would remain the responsibility of FSANZ. The panel suggests that as a first step FSANZ might explore the possibility of using its existing Stakeholder Engagement groups to discuss issues related to context and problem formulation.

2. Strengthen cross-functional coordination at the context setting and problem formulation stage of risk assessment.

The panel noted in its discussion with FSANZ and its international comparators that responsibilities for different aspects of risk assessment are often split across different teams or across institutional boundaries. The panel notes that this has the potential to impede progress in the development and application of modern and responsive approaches to risk assessment. The panel therefore recommends that, in the context

setting and problem formulation stage, all disciplines including nutrition contribute openly in order to facilitate pooling of expertise relating to nutrition, food safety, dietary modelling, and social and behavioural sciences. Within this cross-functional approach, problem formulation should specifically consider food and dietary pattern issues.

3. Prioritize prospective work to promote and protect health, alongside statutory time-bound application work.

The panel believes that application timelines should not crowd out proactive, prospective work that is central to public health protection. The panel therefore strongly supports the approach set out in the Roadmap to 2030, which identifies key proposals to be developed over the coming four years.

Approaches to risk assessment

4. Use problem formulation to drive decision-oriented thinking throughout the nutrition risk assessment process.

The panel advocates for a more decision-led, problem-formulation-driven, and context-integrated approach to nutrition risk assessment. This recognises that, among other things, risk assessment should aim to address the problem statement and within the context that is identified in the upstream process. Keeping sight of the problem statement and its context throughout the risk assessment process will help ensure that the risk assessment is always purposive and that its output is useful to risk managers. The identification of all relevant questions through a robust and cross-functional problem formulation approach is not pre-determined by the risk assessment tools available. It is likely that data will not be available for risk assessors to address in its initial risk assessment all of the questions identified in problem formulation. However, the unanswered questions should then inform the development by risk assessors of hypotheses that can be tested as further knowledge is gained and data are collected, for example through post-market monitoring and surveillance.

5. Make greater use of contingent (or scenario-based) risk assessment and options appraisal.

Scenario-based approaches enable assessment of residual risk following different potential policy interventions or other regulatory measures when used alone and in combination. This would be a key consideration for risk managers, when they consider the likely impact and effectiveness of those interventions and measures. In current practice, developing food standards appears to be the primary risk management approach used by FSANZ, rather than any of the other risk management actions and interventions that FSANZ is empowered to make in response to nutrition risk assessments. Greater use of contingent (or scenario-based) risk assessment would add to the evidence for options appraisal by risk managers, in terms of the likely

differential effectiveness of different risk management approaches in managing or mitigating food safety and nutrition risks, including but not limited to the development of a standard.

Reporting nutrition risk assessments

6. Maintain rigorous, structured, critical evidence review and synthesis to address risk assessment questions.

In the view of the panel, this approach (rather than a formal systematic review) appears as an appropriate approach for the majority of nutrition risk assessments, in the light of resource availability and the urgency of the risk assessment of questions that are often posed.

7. Transparency in the range of safeguards employed for scientific judgements.

As with other aspects of risk assessment, drawing a conclusion in nutrition risk assessment requires scientific judgements. Those made as part of nutrition risk assessment must be demonstrably sound and robust. FSANZ uses a range of safeguards to ensure the robustness of scientific judgements made in nutrition risk assessment, including internal peer review, public consultation processes, external expert advice, and external peer review. The panel recommends that FSANZ develops and makes publicly available the criteria is uses to determine which safeguard(s) should be used and in which circumstances.

Skills and competencies

8. Continue to build the skills and competencies of a strong core nutrition risk assessment team.

The panel was struck by the range and depth of the skills and competencies in the FSANZ executive teams it spoke to, particularly given that FSANZ is a relatively small organisation when compared to its international peers with the added dimension of a transboundary remit. The skills and competencies of the core nutrition risk assessment team in particular should be maintained, to continue to facilitate both the assessment of individual applications, and the scoping and execution of proposals that ask broader nutrition risk assessment questions.

Resource-dependent recommendations

9. Enhance nutrition risk assessment processes to address questions related to chronic disease risk.

Problem formulation for nutrition risk assessment will frequently identify questions related to chronic disease risk. When undertaking nutrition risk assessment of a whole food or complex mixture, FSANZ currently does so by comparing the food to the conventional counterpart food that has a history of safe use as the benchmark, rather than *ab initio,* with a focus on toxicological risk assessment. The future approach should also aim to address nutritional concerns, such as the impact of the food on healthy dietary patterns, and the consequent impacts on NCD risk. The proposed approach to problem formulation that will identify such questions may be implemented at low or no cost and within current capabilities. However, the development and implementation of new tools and approaches for nutrition risk assessment to address these questions, such as assessing the potential long-term consequences of food consumption using both processed-based and nutrient-based approaches, may be resource dependent.

10. Enhance post-market monitoring and surveillance, as part of a continuous process for approvals of novel foods and ingredients.

The panel noted the current limits to *a priori* consideration of the potential impacts of novel foods and ingredients on dietary patterns. In a rapidly changing food environment, it is difficult to judge how well new products will fare in the market. The panel proposes the introduction of post-market monitoring, particularly for foods likely to displace traditional foods in the diet. This monitoring should aim to assess the penetration of novel foods and ingredients into the Australia and New Zealand food supply, and should also aim to provide updated information on food composition and processing at the level of individual products. The Annual Tracker Survey is an existing tool available to FSANZ to identify longitudinal trends in consumer behavior, but would not be sufficient on its own. The FSANZ Act 1991 includes provisions for FSANZ to undertake functions relating to the monitoring and surveillance of food. The enhancement to post-marketing monitoring and surveillance recommended by the panel would require new, ongoing funding, although costs may be offset if these activities are undertaken in collaboration with food manufacturers. The characteristics of foods and dietary patterns to be included in monitoring and surveillance should be focused on those issues which arise as questions in the problem formulation stage in the consideration of applications and proposals.

11. Enhance and complement the collection and analysis of data in National Nutrition Surveys.

These surveys provide valuable information on food consumption trends and health that are informative to context setting and problem formulation. Analyses of these surveys can help identify foods associated with risks to healthy dietary patterns and thereby establish focus and priorities for detailed nutrition risk assessment. The panel proposes that the ability to identify and track trends in dietary patterns and in market penetration of new foods and new food formulations should be a particular focus when designing the collection and analysis of National Nutrition Surveys data. The panel also recommends multi-source integration of food consumption data, as food balance sheets, retail scan data, online 24-hour recall tools and targeted surveys each capture different aspects of intake and product availability thus combining them through market-weighted or scenario-based modelling can partially offset weaknesses in any single source. In the future, FSANZ should also look to leverage technology-assisted individual tools (e.g. web- or app-based recalls with automated coding) to generate more frequent but lighter-touch updates that can be linked to these complementary datasets.

12. Further develop food composition databases.

Comprehensive food databases are fundamental to nutrition risk assessment. There are broadening needs for information on commercial foods including in relation to food additives. Continuing to develop food databases from a range of sources will enable analyses on trends relating to both raw and prepared foods as well as commercial products.

13. Establish a process for oversighting and for analysing the cumulative impacts of regulatory decisions on the supply and consumption of discretionary foods.

The panel hypothesizes that incremental food innovation will over time lead to changes in the range of food on sale, shifts in dietary patterns and potential changes in NCD risk. A formal process to oversight the portfolio of regulatory decisions informed by nutrition risk assessment, with triggers that relate to the periodicity of oversight or to volumes of applications of certain categories of food innovation, would assist in assessing and examining the cumulative impacts of food innovation and the changing food supply on dietary patterns, and with the identification of dietary patterns and the foods within them that promote and protect health. The Evaluation Framework for the Food Regulatory System currently under development by FSANZ might provide a useful framework for any assessment of cumulative impact of decisions relating to applications. In particular, the framework would require any such evaluation to be evidence-based, transparent, focused on learning, and undertaken in partnership with stakeholders. Evidence for such activity would also be facilitated by the enhanced post-marketing monitoring and surveillance approaches described above.

Future opportunities for international coordination

A. Convene an international community of practice. The participants in the semi-structured discussions from other national food regulatory organizations uniformly demonstrated a high level of engagement and expertise, a commitment to collaboration, and a desire to learn from any recommendations the panel may make. The panel proposes that FSANZ convenes an international community of practice to facilitate further collaboration and shared learning. A community of practice, once established, may provide an opportunity to pilot activity and learn in collaboration with other, like-minded national food regulators.

B. Lead international collaborations to enhance approaches to nutrition risk assessment. Once active, the community of practice described above could be a forum for advancing the development of nutrition risk assessment approaches from a first-generation, assessment-oriented paradigm towards the decision-led, problem-formulation-driven, and context-integrated approach proposed by the panel. The panel sees opportunities for FSANZ to lead future-focused discussions and collaborations on nutrition risk assessment within such a community. A plurilateral consideration of the development of nutrition risk assessment approaches may also mitigate some of the risk of otherwise unilaterally developing a nutrition risk assessment approach that may disrupt existing trade patterns.

C. Engage in plurilateral and multilateral discussions on food regulation and ultra-processed food. The panel found a universal acceptance among the national food regulatory organizations it spoke to that the categorization of ultra-processed foods and the application of that categorization to regulatory decision-making is the predominant current challenge for nutrition risk assessment. Some shared tools already exist, such as the FoodEx2 food classification database (developed by EFSA and used internationally), which includes aspects of processing to assist in classifying foods. The panel proposes that early discussion in the proposed community of practice could focus on development of shared tools and practical approaches that address these and other emerging challenges for nutrition risk assessment. The panel notes that beyond any future community of practice, the Codex Alimentarius Commission has, as its statutory purpose, the setting of international standards that protect consumer health and facilitate fair practices in food trade. A discussion of food processing and food safety was initiated at the 48th session of CAC in November 2025. The panel anticipates that this discussion will continue at subsequent sessions of CAC and notes that Australia and New Zealand are active and respected members of Codex.

Longer term opportunities in the development of policy and legislation

i. Review the 2013 Policy Statement regarding the Interpretation of Public Health and Safety in Developing, Reviewing and Varying Food Regulatory Measures. The 2013 policy statement mandates FSANZ to "take into consideration

both long-term health impacts and immediate health risks in the development and review of food regulatory measures." The panel has proposed the integration into nutrition risk assessment of a consideration of how dietary patterns may be assessed and integrated into nutrition risk assessment. This includes consideration of the context of how food innovation might change dietary patterns, including the potential for continuing and growing divergence of the Australian and New Zealand diet from dietary guidelines. More recently, Ministers have "acknowledged that a well-designed and efficient regulatory system provides a predictable environment for businesses to thrive, enter new markets and innovate". The panel notes the OECD orthodoxy that governments have a crucial role to play in fostering innovation while ensuring the right guardrails are in place to protect people, and that this requires a forward-looking perspective that is agile, technology-neutral and risk-based to match the expectations of contemporary society. Against this background, the panel would suggest consideration be given to a review of the 2013 policy statement that strikes a contemporary balance between supporting innovation and protecting consumers.

ii. Consider a policy change to allow approvals for new foods or ingredients to be conditional and/or subject to review. The panel notes that, within the context of the more continuous process for approvals of novel foods and ingredients that it proposes, a more responsive regulatory approach would be facilitated if approvals for new foods or ingredients were made conditional (e.g. on the proposer sharing post-market monitoring and surveillance information) and/or subject to review (e.g. to provide opportunities for approval to be withdrawn or new requirements added if post-market monitoring shows greater or adverse impact on dietary patterns correlated with NCD risk). Noting the need to strike a contemporary balance between supporting innovation and protecting consumers, the potential impacts on innovation and trade of such an approach would need to be carefully assessed.

iii. Development of guidance on nutrition standards for food innovation. The panel notes the challenges inherent in striking an appropriate balance between protecting consumers and maintaining an open and permissive approach to food innovation. The panel proposes the development of guidance on nutritional standards, focused on food innovation, as a tool to support a predictable regulatory approach to such products. The panel supports and endorses the elements of FSANZ Roadmap to 2030 which move the regulatory system in Australia and New Zealand in this direction, particularly the aim to deliver:

- clarity for industry and support for safe innovation in the area of formulated supplementary sports foods; and
- risk proportionate pathways for nutritive substances and novel foods to reduce regulatory burden, support innovation and ensure consumer protection.

PART IV: ILLUSTRATIVE APPLICATIONS OF THE PROPOSED APPROACH

Case study 1: Problem definition for the compositional arm of a future proposal to addressing key issues relating to commercial foods for infants and young children

Executive summary

Developing healthy eating patterns in infancy and early childhood is critical for lifelong health. In December 2025, the FSANZ Executive asked the panel to develop a case study which would articulate the framework and problem statement for the compositional arm of a future proposal to address key issues in commercial foods for infants and young children. After discussion, the panel agreed the context was framed by the following issues.

- FSANZ considers both short- and long-term effects in food regulatory measures.
- Australian and New Zealand infant feeding guidelines need to be addressed or are relevant to interpreting "safe and nutritious" in practice.
- There are some existing compositional requirements in the Code.
- There are timely opportunities for international collaborations on relevant standards, particularly given the intention of the relevant Codex committee to review international standards relating to these foods.
- A DoH publication on these foods provides evidence of emerging problems.

The panel then defined the problem around the following questions:

- What is the nutritional contribution of these foods and how can nutrition risks be characterized, considering scenario-based risk assessment approaches?
- How should the key questions to be framed? Should a food composition framing be used, within which one might ask to what extent these foods replace core foods in the diet and whether they should be treated as discretionary foods, within the meaning ascribed to this term in dietary guidelines? Should a regulatory framing be used, within which one might ask, in the eventuality that these foods are regulated, whether they become special purpose foods within that category of the Code, and whether this would be a desirable outcome? These, and potentially other approaches to framing key questions, are not mutually exclusive but might be used to provide complementary perspectives on the issue.
- What are the risks associated with negative nutrients in the diet for this population group?
- Do portion size, hyper-palatability, and marketing practices contribute to overconsumption and increase obesity risk?

- Which risk management tools are available (standards, labelling, guidance, reformulation levers, procurement, monitoring), and what would be the likely effectiveness of each?

Outputs of this problem formulation would guide the subsequent steps of the risk analysis process (see Figure 6.1), drawing on the capabilities of the FSANZ teams (particularly dietary modelling) and relevant networks. Evaluation of this process would contribute to iterative improvement and stronger collaboration with international counterparts.

The case study

Introduction

In December 2025, the FSANZ Executive asked the nutrition risk assessment review panel to develop a case study which would articulate the framework and problem statement for the compositional arm of a future proposal to address key issues in commercial foods for infants and young children (CFIYC):



Throughout its report, the panel advocates for an approach that includes engagement with stakeholders throughout the process of problem formulation, distinct from and in addition to the statutory consultation process. The panel envisages an approach in which FSANZ sets out the context or framework for the risk assessment, following

which issues relating to problem formulation, as a key element of risk governance, are discussed with external stakeholders through a consultative and publicly transparent process.

This would aim to socialise the issues involved and help stakeholders to understand the context and framing of the issue, which would remain the responsibility of FSANZ. It would require a clear distinction to be drawn between those elements which are set and predetermined by FSANZ in terms of the regulatory and wider context of the issue under discussion, and those elements which are the subject of the proposed early engagement and perspective gathering to inform problem formulation by FSANZ. While this approach would not be needed for every issue, it should be incorporated into existing practice when dealing with major, novel or contentious issues such as the proposed review of CFIYC.

This case study provides an opportunity for the panel to indicate how its recommendations relating to context setting and problem formulation would work in practice.

In setting the context and framing problem formulation, the panel has taken a holistic view that supports consideration not only of whether any food is safe in isolation, but how assessors may then determine the effects of dietary patterns, food trends and innovation on the diet.

Setting the context for nutrition risk assessment

The temporal and developmental context for nutrition risk assessment of CFIYC

To put the issue in a temporal context, introduction of these foods would follow a period of breastfeeding, where under healthy normal circumstances breastmilk, with its naturally and evolutionarily optimised composition, provides the complete nutritional needs of infants from birth to 4-6 months of age. Over recent decades advances in science have exposed the presence, 'dose' and function of the many biological components in breastmilk, and this knowledge continues to grow. The development of breastmilk substitutes has likewise developed as this knowledge expands, but these products will always be lagging advances in scientific knowledge which, in themselves, can only ever give a partial picture of the composition of breastmilk.

In addition to meeting nutritional needs, breastfeeding also addresses significant psychosocial and physical developmental imperatives, including human bonding, the development of certain motor skills such as sucking and swallowing, and the development of the infant gut (including microbiome).

After the first 4-6 months the infant has developed to a stage where additional foods may be required to meet increasing nutritional requirements, in particular energy (due

to size and activity), and iron (a limiting nutrient in breastmilk). There is also a need to address new stages of psychomotor and social development (including grasping, swallowing ability, social interaction and belonging) as well as managing a window of opportunity to exposures for learning tastes, textures and developing resistance to potential allergens. These factors may have significant long-term effects on health, directly or indirectly.

Information about introducing solids to infants is contained in the Australian and New Zealand infant feeding guidelines - *Eat for Health: Infant feeding guidelines*, and *Eating and Activity Guidelines*, respectively. These recommend that infants should be offered a range of foods of an appropriate texture and consistency for their developmental stage. Infant feeding guidelines also recommend first foods be iron rich and that an increasing range and quantity of foods should be introduced so that by 12 months the infant is consuming a wide variety of family foods.

The infant feeding guidelines caution that infants given salty or very sweet foods may acquire a taste for them, resulting in poor food choices later in life. They recommend solid foods should be provided to children without the addition of sugar or honey, noting that consumption of added sugars is associated with poor dietary quality, obesity, increased risk of NCDs and increased dental caries. The infant feeding guidelines also recommend avoiding added salt to foods for infants, and to choose lower salt options when available. This is due to the limited maturity of infant's organs, particularly the kidneys, and their ability to conserve fluids and excrete sodium. Excess sodium in the diet can also increase the excretion of calcium.

After 2 years, diets should be aligned with dietary guidelines. CFIYC may therefore form part of the diets of infants and young children in the critical period between exclusive breastfeeding at around 6 months of age and dietary patterns aligned with the ADG at 2 years of age. CFIYC may provide many infants with their first taste experience beyond breastmilk or formula and may form an ongoing proportion of their diet.

The diet of the young child approaching 2 years of age, and the role of CFIYC within that diet, should therefore support the transition to a diet aligned with dietary guidelines.

There is growing evidence about interventions to transform outcomes in later life for this vulnerable population. Optimal maternal and child nutrition is a key pillar to shape wellbeing, with benefits including improved cognitive, motor and socioemotional development, improved school performance and learning capacity, decreased obesity and NCDs, and increased work capacity and productivity.

Current regulatory provisions

Sections 2.9.1, 2.9.2 and 2.9.3 of the Food Standards Codex regulate, among other things, follow-on formula, foods for infants, and formulated supplementary foods for

children aged 1 to 3 years (FSANZ n.d.). In each case, the Code sets out some compositional requirements for these foods. These include:

- limited circumstances in which follow-on formula may contain medium chain triglycerides and added fructose and/or added sucrose;
- minimum and maximum levels for specified nutritive substances in follow-on formula;
- minimum and maximum levels iron and vitamin C, a prohibition on added salt and maximum levels of simple sugars and sodium in specified categories of foods for infants up to 12 months; and
- minimum protein levels per serving in formulated supplementary food for children aged 1 to 3 years.

In summary, the Code sets some limited compositional requirements for only some specific categories of commercial foods for infants and young children. Foods designed for children older than 12 months do not have the same compositional requirements as those for infants up to 12 months.

Relevant international standards

International commodity and compositional standards for a range of commercial foods for infants and young children have been adopted by the Codex Alimentarius Commission (CAC), following their development by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). These standards are voluntary in nature and require incorporation into national legislation to have effect; nevertheless they are reference texts in the case of World Trade Organisation dispute arbitration. The three CAC texts related to complementary feeding of older infants and young children are:

- Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991);
- Standard for Canned Baby Foods (CXS 73-1981); and
- Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981).

In 2024, CAC endorsed a proposal from CCNFSDU for new work in that committee to develop a standard for foods for older infants and young children. The scope of the new standard would be baby foods, processed cereal-based foods, complementary foods for older infants and young children including but not limited to meat, vegetable, fruit or pulses-based products, and foods for older infants and young children. This new standard would not apply to follow-up formula and product/drink for older infants and young children, as CAC had adopted revised standards for these products in 2023. The new work will take into consideration the existing three Codex texts in developing a single, new, comprehensive standard for foods for older infants and young children. Its scope will include foods being offered for sale that were not covered by the existing

standards and it aims to ensure that foods for this age group are safe and nutritionally adequate.

Some concerns were expressed by Codex member countries that the development of the standard should not lead to the promotion of processed foods as an alternative to resolving nutrition conditions for older infants and young children or lead to replacement of home-based foods or affect the promotion of breastfeeding. It was also requested that the standard consider the recommendations of the United Nations Children's Fund (UNICEF) (UNICEF 2021) and WHO, which relate to matters including:

- Protecting children from marketing of unhealthy foods, including through implementation of the *WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children*;
- use of fiscal measures to encourage healthy diets and discourage consumption of unhealthy products; and
- reformulation of processed foods, including portion sizes.

Problem formulation

The current state of play

The 2020 paper, *Commercial foods for early childhood: Australia and New Zealand*, developed by the Australian Government Department of Health, summarised the environment at that time relating to infant and toddler nutrition in Australia and New Zealand, including examining commercially available foods for children aged 4 to 48 months (DoH 2020).

The paper noted that commercially available foods for infants and toddlers play an important part in the nutrition of children in Australia and New Zealand, and acknowledged the provisions and the protection provided by compositional and other requirements of the Food Standards Code.

Key findings relating to the composition of commercially available foods for infants and toddlers included:

- Commercial foods frequently prioritise sweet flavours for 'meals', which creates issues for setting the palate and lifelong taste preferences.
- Commercial infant foods may be a major contributor of sugar to the diet, using processed fruit products and sugar to sweeten goods.
- Manufacturer recommended serving sizes are often far larger than recommended in dietary guidelines and infant feeding guidelines. Even when sugar is not added, having large servings promotes overconsumption of food and increase the amount of sugar consumed.
- While some finger food products contain added salt, overall salt was not a concern across any of the categories.

- Yoghurt pouches marketed to children often contain added sugar, although some reformulation work has been undertaken.

The paper highlighted that commercially available products in supermarkets are playing to instinctive preferences for a sweet flavour profile and setting lifelong preferences for sweet foods, which is known to be associated with negative health conditions. Large serving sizes may also be driving overconsumption of foods. The paper noted that addressing these issues has the potential to translate into long term health outcomes for future generations.

These evidence-based conclusions should be supplemented by any available further evidence relating to the composition of currently available CFIYC relating to:

- the extent to which the composition of individual CFIYC would be considered to have excessive levels of sugar, salt and/or fat when compared to the home-prepared foods that they replace or supplement in the diets of this population group;
- the extent to which consumption of CFIYC is associated with overconsumption and/or with dietary patterns that are associated with life-long NCD risks.

Issues relevant to problem formulation

While problem formulation remains the responsibility of the FSANZ Board and Executive, this critical stage in risk analysis should be informed by open and consultative processes that aim to engage all relevant stakeholders, including from the parts of the food industry who produce and sell CFIYC as they have significant relevant technical knowledge. The content and conduct of these processes should reflect the importance of this issue, given that compositional standards for CFIYC should not only consider the need to meet nutritional requirements in this critical life stage, but also the very significant potential impact of food habits established in this period of life on lifelong dietary patterns and associated NCD risk.

The following issues and questions related to the composition of CFIYC should feature in this consultative phase:

- The recommendation in infant feeding guidelines is that an increasing range and quantity of foods should be introduced at weaning so that by 12 months the infant is consuming a wide variety of family foods. Balanced against this focus and exclusive reliance on family foods are a number of arguments. For example, CFIYC provide convenience which is highly valued by many parents and care-givers. Also, evidence shows there are very real challenges in introducing family foods to toddlers, and CFIYC may support this transition.
- Which family foods do CFIYC replace in a child's diet? Does this raise concerns relating to infant feeding guidelines recommendations relating to:
    - consumption of a wide variety of foods by 12 months of age;

    - cautioning against offering salty or very sweet foods to children, who may then acquire a taste for them and, in the case of salt, noting the limited maturity of infant's organs, particularly the kidneys, and their ability to conserve fluids and excrete sodium;
    - recommending against addition of sugar or honey, as consumption of added sugars is associated with poor dietary quality, obesity, increased risk of NCDs and increased dental caries; and
    - control of portion size.
- Recent research in other developed markets has shown that the use in CFIYC of food additives that increase the organoleptic appeal of those products (i.e. flavour enhancers, emulsifiers, thickeners and colours) has increased more markedly than in other food and beverage categories over the past two decades (Dunford et al. 2026). This has coincided with a very significant increase in the availability and variety of CFIYC over the same period. What are the implications of consumption of CFIYC beyond nutrient composition, including in shaping taste preferences and dietary patterns in ways that favour consumption in later life of discretionary foods high in sugar and sodium?
- Is there a risk that CFIYC, due to large, recommended portion sizes and/or to the hyper-palatability of those foods when compared to foods in their natural state due to their formulation, lead to overconsumption?
- What is the nutrition contribution, both positive and negative, of CFIYC to the total diets of this population group, their dietary patterns while infants and young children, and their dietary patterns and NCD risks in later life? In terms of nutrition risk assessment methodology, how might these risks be characterised?
- What would be the most appropriate risk management tools (amendments or additions to the Food Standards Code, guidelines, Codes of Practice) to address any nutritional risks related to the composition of CFIYC? Should risk assessment aim to advise on the likely effectiveness of a range of policy interventions or other regulatory measures, either alone or in combination, and the extent to which residual risk to consumers of CFIYC changes under alternative interventions?

For the avoidance of doubt, problem formulation is an integral part of risk management policy and so remains the sole responsibility of FSANZ, which is the body so tasked by statute. The purpose of the early engagement process is to ensure that the identification of contextual considerations that should inform problem formulation benefits from the range of perspectives that external stakeholders will bring.

References for Case Study 1

DoH (2020) Commercial foods for early childhood: Australia and New Zealand, Department of Health, Canberra. https://www.foodregulation.gov.au/sites/default/files/2023-09/commercial-foods-for-early-childhood-australia-and-new-zealand_0.pdf

Dunford EK, Pries A, Calvo MS and Coyle DH (2026) Tiny Tummies, Big Questions: Unpacking Ultra-Processed Ingredients and Additives in Complementary Foods in the United States, *Nutrients*, 18(4):584, doi: 10.3390/nu18040584.

FSANZ (n.d.) The Food Standards Code legislation, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/food-standards-code/legislation

UNICEF (2021) UNICEF technical note on effective regulatory approaches to protect, support and promote better diets and create healthy food environments for children, UNICEF, New York. https://www.unicef.org/documents/effective-regulatory-approaches-food-environments

Case Study 2. Ultra-Processed Foods (UPFs): Problem Formulation, Competing Mechanisms, and Implications for Risk Governance

Executive summary

This case study considers how FSANZ could approach the issue of ultra-processed foods (UPFs) within an enhanced risk analysis framework that is explicitly decision-led, hypothesis-neutral, and proportionate to uncertainty. The central proposition is that the current debate around UPFs often moves too quickly from epidemiological association to causal explanation. From a regulatory perspective, this creates a risk of asking the wrong question.

Accordingly, this case study does not begin from the assumption that food additives, additive mixtures, nutrient profile, processing level, texture, or any other single feature of UPFs is already known to be the principal driver of adverse health outcomes. Instead, it begins from a prior regulatory question: **which characteristics of UPFs, if any, are plausibly associated with adverse dietary and health outcomes, and which of those characteristics are sufficiently evidence-based, decision-relevant, and governable to justify structured assessment and possible intervention?**

On that basis, the case study identifies several non-mutually exclusive explanatory pathways, including nutrient composition and energy density, food structure and texture, eating rate, hyper-palatability, dietary displacement, broader food-environment factors, and additive-related mechanisms. Additive-related concepts such as additive load and functional stacking are positioned as candidate analytical tools, not as pre-established causal mechanisms.

Recent evidence from the food additive mixtures literature materially strengthens the rationale for including additive-related mechanisms within this broader comparative assessment. Multiple sources indicate that consumers are routinely exposed to mixtures rather than single substances, that additive co-occurrence in foods is common and structured, that some experimental and epidemiological findings raise plausible questions about combined effects, and that regulatory science is progressively moving toward more mixture-aware surveillance and assessment methods (Chazelas et al. 2020; COT 2008; Payen de La Garanderie et al. 2025; Samoylov and Suraeva 2024; Shaw 2014). At the same time, this literature does **not** establish additive mixtures as the dominant explanation for UPF-related health effects.

The case study therefore concludes that the appropriate response for FSANZ is neither to dismiss additive-related concerns nor to presume them. Rather, FSANZ could adopt

a staged approach that compares competing mechanisms, improves post-market intelligence, and uses additive-related indicators only where they add explanatory or governance value beyond other candidate pathways. This case study thus illustrates a broader lesson for modern risk governance: when food-related concerns arise from complex systems rather than single hazards, the quality of **problem formulation** becomes central to the quality of downstream decisions.

1. Introduction

1.1 Purpose of the case study

The purpose of this case study is to demonstrate how FSANZ could approach the issue of UPFs using an enhanced framework for problem formulation and system-level risk governance. The chapter is intended to show how a regulator can engage with a scientifically and politically contested issue without collapsing prematurely into a single causal narrative.

More specifically, the case study seeks to:

a. identify the principal competing and complementary hypotheses proposed to explain the association between UPF consumption and adverse health outcomes
b. assess which of these hypotheses are sufficiently plausible, evidence-supported, and decision-relevant to warrant structured analysis
c. examine whether additive-related constructs such as additive load and functional stacking provide useful explanatory or governance value
d. illustrate how risk assessment and risk management could be linked under conditions of uncertainty without prematurely fixing the mechanism of concern.

This case study is not intended to provide a definitive causal determination. Nor is it intended to propose immediate regulatory prohibition or revision of existing additive authorizations. Its function is to support **problem formulation**.

1.2 Why this issue matters for FSANZ

Food regulation has historically been strongest where the hazard can be clearly specified. Traditional frameworks developed by WHO, FAO, Codex Alimentarius, JECFA, EFSA, FDA, and related bodies are well suited to the assessment of individual hazards such as foodborne pathogens, contaminants, residues, or authorized additives used under defined conditions (EFSA 2026; Codex CXS 192-1995; JECFA monographs; FDA 2026).

In the food additive domain, the standard logic is substance-based: identify the additive, assess toxicology, derive a health-based guidance value where appropriate, estimate exposure, and judge whether the intended use is acceptable.

The challenge raised by UPFs is different. The concern is not, in the first instance, that a single additive exceeds an Acceptable Daily Intake (ADI), or that a single product contains a prohibited constituent. Rather, the concern is that some foods produced through modern industrial formulation appear to be associated with broader dietary and health effects. This requires a different analytical stance, because the issue may lie not in one component but in a combination of product characteristics, usage patterns, and food-environment conditions.

1.3 Scope and limits

This case study is confined to the **problem formulation and assessment design stage**. It does not:

- re-evaluate individual additive toxicology
- undertake new exposure modelling
- provide a legal analysis of amendment pathways under the FSANZ Code
- recommend immediate product-specific restrictions.

Instead, it uses available scientific and regulatory literature to clarify how FSANZ might define the problem in a way that is analytically robust and decision relevant.

1.4 Relationship to the broader review

This case study should be read in conjunction with the broader review sections on:

- problem formulation
- iterative evidence integration
- uncertainty analysis
- continuous communication
- the interface between risk assessment and risk management.

The present case study operationalizes those principles in the specific context of UPFs.

2. Reframing the UPF question

2.1 From category-based concern to mechanism-oriented inquiry

UPFs are often discussed as if the category itself were the object of regulation. However, from a regulatory standpoint, category labels do not constitute mechanisms. A classification such as NOVA may be useful descriptively, but it does not tell FSANZ which feature of a product is responsible for harm, nor which intervention would be proportionate and effective.

The first analytical step is therefore to move from **category-based concern** to **mechanism-oriented inquiry**. The relevant question is not simply whether UPFs

are associated with adverse outcomes, but what it is about some UPFs that may matter.

2.2 The risk of premature causal narrowing

A recurring difficulty in the UPF debate is the tendency to move directly from epidemiological association to implied causal explanation. Yet the possible explanatory features of UPFs are numerous and overlapping. These include:

- nutrient profile
- energy density
- food form and texture
- oral processing characteristics
- hyper-palatability
- displacement of minimally processed foods
- additives and additive mixtures
- convenience, packaging, marketing, and availability.

Selecting one of these features at the outset and building the assessment around it creates a substantial risk of analytical bias. The role of problem formulation is precisely to prevent this from happening.

2.3 Working question for FSANZ

For the purposes of this case study, the core framing question is:

Which characteristics of UPFs, if any, are plausibly associated with adverse dietary and health outcomes, and which of those characteristics fall within the practical scope of food regulatory assessment and governance?

This framing is deliberately upstream of any additive-specific or nutrient-specific conclusion.

3. Competing and complementary explanatory pathways

3.1 General approach

At the problem formulation stage, FSANZ would need to treat the UPF issue as involving multiple plausible and potentially interacting hypotheses. These hypotheses are not mutually exclusive. They may operate together, vary by food category, or differ in importance across population groups.

3.2 Nutrient composition and energy density

One possible explanation is that the observed health associations are driven largely by poor nutrient profile and high energy density. Many UPFs contain excess free

sugars, sodium, saturated fats, or combinations thereof, and these features are established drivers of excessive intake and poor dietary quality. This remains a strong explanatory candidate and is consistent with evidence that energy density is a major determinant of energy intake (Rolls et al. 2020).

3.3 Food structure, texture, and eating rate

A second explanation concerns the physical properties of foods. Texture, hardness, lubrication, and structural integrity affect oral processing and eating rate, which in turn influence intake. Bolhuis and Forde (2020) and Forde and Bolhuis (2022) have argued that texture and food matrix properties can materially alter energy intake and metabolic responses. Lasschuijt et al. (2023) found markedly lower energy intake under hard-texture compared with soft-texture conditions, while Forde et al. (2026) showed that modifying eating-rate properties within UPF diets changed daily intake by 369 kcal/day. This suggests that some relevant mechanisms may arise from **processing-enabled product properties** rather than processing level as such.

3.4 Hyper-palatability and reward-related responses

A third explanation focuses on hyper-palatability and reward. Certain combinations of ingredients, sensory properties, and nutrient levels may generate reinforcing responses that promote continued intake beyond homeostatic need. Fazzino et al. (2019) proposed criteria for identifying hyper-palatable foods, while Demeke et al. (2022) documented the increasing prevalence of such foods in the US food system. Jun, Knowles and Fazzino (2025) further explored these features using global crowd-sourced data.

3.5 Dietary displacement and whole-diet effects

A fourth hypothesis is that the health significance of UPFs lies partly in their role in displacing minimally processed foods and reshaping dietary patterns. Under this view, the issue is not only product composition but habitual substitution, meal structure, fiber dilution, and cumulative changes in overall diet quality.

3.6 Broader food-environment drivers

A fifth explanation places greater weight on convenience, affordability, ubiquity, packaging, marketing, and the social organization of food choice. These factors may interact with product-level properties but are conceptually distinct from them. They may also sit only partly within FSANZ's direct regulatory remit.

3.7 Additive-related mechanisms

A sixth explanation concerns additives and additive mixtures. Here it is necessary to distinguish among several sub-hypotheses:

a. additives may have direct biological effects when consumed in combination
b. additive mixtures may exhibit additive, synergistic, or antagonistic toxicological effects not captured by single-substance evaluation
c. additives may enable product properties such as sweetness, texture, stability, flavor persistence, and shelf life that indirectly affect intake and dietary patterns.

These propositions should be treated as **candidate mechanisms**, not established conclusions.

4. Why additive-related mechanisms warrant examination without prior assumption

4.1 Real-world exposure occurs through mixtures

A key reason additive-related mechanisms deserve consideration is that actual dietary exposure does not occur substance by substance. The UK Committee on Toxicity (2009) stated that traditional approaches do not reflect the "real-life situation" in which people are exposed to multiple chemicals simultaneously. Shaw (2014) similarly argued that an average meal may contain a "cocktail" of residues, additives and natural toxicants with potential additive or synergistic effects. Reviews focused specifically on food additive mixtures conclude that the toxicological significance of such combinations remains unresolved and merits further research (Samoylov and Suraeva 2024).

This does not establish additive mixtures as the main explanation for UPF-related outcomes. It does, however, support their inclusion as a credible line of inquiry.

4.2 Additive co-occurrence in foods is common and structured

Market-level evidence strengthens this point. Chazelas et al. (2020), in an analysis of 126,556 packaged food and beverage products in France, found that 53.8% contained at least one additive and 11.3% contained five or more. Co-occurrence was not random. The authors identified six recurring additive clusters corresponding to food types such as sweets, biscuits and cakes, sugar-free chewing gums and artificially sweetened beverages, instant noodles and umami foods, and processed meat (Chazelas et al. 2020).

This is important because it indicates that additive mixtures are a routine feature of the contemporary food supply and that realistic cluster-based monitoring or testing is feasible.

4.3 Population exposure studies identify recurring mixture profiles

Exposure studies also show that additive mixtures can be characterized in real diets. Using nationally representative French data, Payen de La Garanderie et al. (2025) identified three principal additive mixtures in adults and four in children. These profiles reflected recurring combinations of technological functions and food uses, demonstrating that additive exposure is structured and measurable at population level.

Again, this is not evidence of harm by itself. It is evidence that additive-related exposure constructs are empirically tractable.

4.4 Toxicological evidence is heterogeneous and context-dependent

The toxicological evidence on additive mixtures remains mixed. Recoules et al. (2024), examining additives alone and in mixtures across four human cell models, found heterogeneous outcomes, with some mixtures showing no cytotoxic or genotoxic effect, one showing cytotoxicity, and two showing genotoxicity at the highest tested concentrations. The observed effects were not attributable simply to relative component concentrations. Salih (2006) reported context-dependent photo-genotoxic effects under sunlight exposure. Some animal studies found no synergy under specific acute toxicity designs (Sado 1973), whereas others suggested enhanced organ toxicity or biochemical disruption in repeated co-exposure settings (Ershoff 1976; Radwan et al. 2020).

The relevant conclusion for FSANZ is therefore not that additive mixtures are uniformly hazardous. It is that their behavior appears insufficiently captured by a simple extrapolation from single substances alone.

4.5 Epidemiology is beginning to test mixture-based exposure

Human epidemiology is also moving toward mixture-based analysis. In the NutriNet-Santé cohort, two additive mixture profiles were associated with higher type 2 diabetes incidence, with exploratory indications of synergistic and antagonistic interactions, while the authors appropriately acknowledged residual confounding and exposure misclassification as limitations. Reviews have also discussed behavioral concerns around mixtures of artificial colors and sodium benzoate in children (Samoylov and Suraeva 2024).

These findings do not justify causal claims. They do justify further structured inquiry.

4.6 Regulatory science is increasingly mixture-aware

Regulatory systems remain largely substance-based, including the EU framework for food additives, Codex standards, JECFA monographs, and FDA petition guidance

(EFSA 2026; European Commission materials; Codex CXS 192-1995; FDA guidance). However, methodological developments indicate increasing readiness for mixture-aware surveillance and exposure refinement. FACET was explicitly developed as a post-market tool to reflect actual exposure using real concentration and occurrence data rather than maximum permitted levels alone. EFSA's RACEMiC roadmap similarly indicates that mixture-risk assessment readiness for food additives may be relatively high compared with some other domains (de Jong et al. 2022).

For FSANZ, the practical implication is that additive-related hypotheses could be approached initially through smarter surveillance and prioritization rather than through wholesale redesign of the authorization system.

5. Candidate additive-related constructs

5.1 Additive load

For the purposes of this case study, **additive load** refers to the number, diversity, and frequency of additives consumed over a defined period at the diet level. It is a descriptive construct. It does not imply that a higher additive count is intrinsically harmful. Its potential value lies in helping FSANZ examine whether some diets, food categories, or population groups are characterized by recurrently higher cumulative additive exposure.

5.2 Functional stacking

Functional stacking refers to the co-occurrence within a product of additives performing different technological functions, such as emulsification, stabilization, sweetening, preservation, coloring, or flavor enhancement. This construct is relevant only insofar as such co-occurrence may:

- enable product properties linked to overconsumption or dietary displacement
- create exposure constellations not captured adequately by single-substance perspectives
- or both.

5.3 Analytical status of these constructs

A critical rule applies throughout this case study: the existence of additive load or functional stacking does not establish causality. These constructs are used here as **descriptive and hypothesis-testing tools**, not as conclusions about mechanism.

6. Decision-led problem formulation

6.1 Primary question

The proposed primary question for FSANZ is:

How can FSANZ determine which features of UPFs are most plausibly relevant to adverse dietary and health outcomes, and whether any additive-related factors contribute sufficiently to warrant targeted assessment, surveillance, or governance action?

6.2 Secondary questions

The primary question gives rise to several secondary questions:

a. Which hypothesized features of UPFs are most strongly supported by current evidence?
b. Which of these features are modifiable through food standards or broader risk governance tools?
c. To what extent do additive-related indicators improve understanding of UPF-related patterns beyond nutrient profile, energy density, food structure, texture, eating rate, and broader dietary-pattern variables?
d. In which food categories and population groups, if any, do additive-related features appear most relevant?
e. What types of evidence would be needed to justify different forms of action, from improved monitoring to targeted intervention?

6.3 Intended outputs

Outputs from such a problem formulation exercise could include:

- a comparative assessment of candidate mechanisms
- identification of priority food categories and population groups
- determination of whether additive-related constructs add explanatory value
- recommendations for surveillance priorities and evidence generation.

7. Evidence integration

7.1 General principle

Evidence integration should be comparative rather than confirmatory. No single data stream can resolve the UPF question. Epidemiology, mechanistic studies, dietary surveys, label data, and monitoring data each contribute differently.

7.2 Consumption and dietary-pattern evidence

Dietary surveys remain central for identifying what people consume, how often, and in what combinations. They can help characterize UPF-heavy diets relative to minimally processed diets, including subgroup differences and long-term exposure patterns. Reviews of additive exposure assessment have emphasized the importance of using actual occurrence levels together with food consumption data and, where possible, multi-day records and food-frequency information (Ekenci and Köksal 2024; Löwik 1996).

7.3 Occurrence and product composition data

If additive-related mechanisms are to be assessed, actual occurrence data are crucial. Tiered models such as FACET show how conservative exposure scenarios can be refined using measured concentrations and real use patterns by food category (FACET materials (NAL n.d.); Vin et al. 2013). Monitoring-based assessments also demonstrate that conclusions can vary materially depending on whether maximum permitted levels or actual market data are used (Lee et al. 2019; Vin et al. 2013).

7.4 Toxicological and mechanistic evidence

Toxicological evidence on mixtures needs careful prioritization rather than blanket inference. Mixture effects appear to vary by endpoint, exposure context, concentration range, and study design (Radwan et al. 2020; Recoules et al. 2024; Salih 2006). In parallel, mechanistic evidence on food structure, texture, and eating rate should be considered, since additives may exert relevance indirectly by enabling product properties rather than by direct toxicological interaction.

7.5 Epidemiological evidence

Epidemiological findings, including mixture-based cohort analyses such as NutriNet-Santé, can help identify potentially relevant pathways but should not be treated as determinative of mechanism. Their main value in this framework is to support prioritization.

7.6 Uncertainty

Uncertainty should be made explicit at each stage, including uncertainty relating to:

- causal inference
- exposure characterization
- occurrence data completeness
- generalizability across food categories
- separation of direct and indirect mechanisms.

8. Implications for risk assessment

8.1 Extending rather than replacing the current framework

This case study does not suggest replacing the current additive risk assessment architecture. Substance-specific toxicological assessment, conditions of use, ADIs, and related exposure analysis remain necessary and valid. The issue is whether they are sufficient, on their own, to address the broader questions raised by UPFs.

The more constructive interpretation is that FSANZ may need a **supplementary assessment layer** capable of examining cumulative exposure patterns, recurring mixture profiles, formulation-related product properties, and their possible interaction with diet-level outcomes. This layer would sit alongside, rather than in place of, existing additive assessment. Its function would be to improve the agency's capacity to characterize system-level concerns that are not easily captured by substance-by-substance evaluation alone.

This is especially relevant where the issue is not the breach of a toxicological threshold by an individual additive, but the possibility that multiple product features, some additive-related and some not, combine to shape population exposure, intake behavior, and long-term health effects. In such contexts, the classical framework remains essential but may need to be complemented by more integrative tools.

8.2 Role of additive-related constructs in prioritization

If additive-related pathways are judged sufficiently plausible to examine further, additive load and functional stacking may be useful at the prioritization stage. Their primary role would not be to establish causation, but to help FSANZ identify where more focused analysis may be warranted.

For example, such constructs could help identify:

- food categories that function as additive exposure hubs
- population groups with recurrently high additive diversity in the diet
- recurring additive clusters warranting focused surveillance
- product types in which additive combinations align with candidate product properties of concern, such as high palatability, soft texture, shelf stability, or high convenience.

Used in this way, additive-related indicators would contribute to screening, prioritization, and hypothesis refinement. They would help determine where the agency might invest analytical effort, rather than serving as stand-alone indicators of risk. This is important for maintaining conceptual discipline. In a complex area such as UPFs, the purpose of early-stage risk assessment is not to collapse complexity prematurely, but to reduce it in a structured and evidence-based way.

8.3 Distinguishing direct and indirect additive-related pathways

A clear distinction should be maintained between two broad routes through which additive-related factors may be relevant.

The first route concerns **direct additive-mixture effects**. Here the concern is that combined exposure to multiple additives may produce biological effects that are not adequately captured by single-substance evaluation. This may involve additive, synergistic, or antagonistic interactions, or more complex response patterns that depend on exposure conditions, endpoints, and mixture composition. The available evidence does not allow broad generalization, but it does support the view that this possibility cannot be excluded a priori (Recoules et al. 2024; Salih 2006; Samoylov and Suraeva 2024).

The second route concerns **indirect formulation-mediated effects**. In this pathway, additives may matter not because they directly produce toxic effects in combination, but because they help create product properties associated with altered intake or broader dietary-pattern change. Additives may contribute to sweetness, flavor persistence, texture modification, viscosity, lubrication, stability, visual appeal, or shelf life, and these properties may in turn influence eating rate, satiety, convenience, or frequency of consumption. In such cases, the regulatory relevance of additives is indirect but still potentially important.

These two routes are conceptually distinct and should not be conflated. They rely on different evidence, call for different forms of modelling, and may imply different governance responses. Preserving this distinction is essential if the assessment is to remain analytically coherent.

8.4 Towards quantitative probabilistic risk characterization

A further implication of this case study is that, where the evidence base is sufficiently developed, FSANZ could move beyond descriptive exposure profiling toward quantitative probabilistic risk characterization. In such an approach, exposure distributions would not be considered in isolation, but linked to the best available dose–response, exposure–response, or epidemiological effect models to estimate the distribution of risk in the population.

For some pathways, this may involve relatively classical toxicological integration. Dietary exposure estimates could be linked to benchmark dose models, margins of exposure, threshold-based reference values, or other health-based approaches, depending on the nature of the endpoint and the maturity of the underlying evidence. For other pathways particularly where epidemiological evidence is stronger than toxicological evidence, exposure distributions could be linked to published relative risk (RR) functions, hazard models, or other population-based response functions. The purpose would be to move from identifying exposure patterns to estimating the likely magnitude and distribution of health impact.

This shift would be particularly valuable where both variability and uncertainty materially influence decision-making. Variability may arise from differences in food consumption, product formulation, additive occurrence levels, body weight, susceptibility, age, dietary pattern, or baseline health status. Uncertainty may arise from incomplete occurrence data, limited knowledge of co-exposure patterns, model choice, imprecision in dose–response estimates, assumptions about extrapolation, or residual ambiguity regarding causal pathways.

A probabilistic framework, including Monte Carlo simulation where appropriate, would allow FSANZ to represent both dimensions explicitly. In such a framework, simulation is not merely a computational convenience. It becomes a core analytical instrument for generating distributions of exposure and risk rather than relying only on point estimates. This would make it possible to characterize central tendencies, upper percentiles, subgroup contrasts, confidence ranges, and the sensitivity of results to key assumptions. It would also improve transparency by making visible which elements of the model are driven by real population heterogeneity and which are driven by evidence limitations.

In practical terms, such an approach could allow FSANZ to estimate, for example:

- the proportion of the population or of specific subgroups falling above or below relevant risk thresholds
- the distribution of exposure across recurring additive mixture profiles
- the uncertainty around estimated risk under alternative assumptions
- the contribution of different inputs to overall model uncertainty
- and the potential public health implications of current versus alternative market or reformulation scenarios.

The use of such probabilistic integration should remain proportionate to the maturity of the evidence base. It will not be feasible for all candidate mechanisms or all additive-related pathways, because the necessary dose–response or exposure–response evidence is not equally available or equally robust across all contexts. However, the framework should be designed so that it can accommodate this type of modelling where the evidence is sufficiently mature. Doing so would create a clear pathway from exploratory problem formulation to more explicit and quantitative risk characterization.

8.5 Potential extension toward integrated risk–benefit assessment

The same modelling architecture could also provide a basis for more integrated risk–benefit assessment where the relevant food exposures involve both potential hazards and potential health determinants. This is particularly important in the UPF context, where interventions may alter several pathways at once and where a narrow hazard-only perspective may fail to capture the full public health picture.

For example, a product reformulation may reduce exposure to a nutrient of concern, lower energy density, or alter food texture in ways that slow eating rate and reduce overall intake. At the same time, it may increase or decrease the use of additives, modify shelf life, change product acceptability, or influence consumption frequency in ways that affect population exposure differently. Likewise, some additive applications may support product designs associated with overconsumption, whereas others may facilitate more favorable profiles, for example through sugar substitution, texture adjustment, or fiber enrichment. The net health effect may therefore depend on how multiple pathways interact, not on one endpoint alone.

In such contexts, probabilistic simulation could be used not only to quantify uncertainty, but also to compare alternative scenarios in terms of their overall health implications. Exposure distributions could be linked to dose–response or relative risk models for adverse outcomes while also incorporating beneficial health determinants where suitable quantitative functions exist. This would make it possible to compare baseline and reformulation scenarios, estimate the probable direction and magnitude of health gain or loss, and identify which uncertainties have the greatest influence on the result.

This orientation would move the framework closer to decision-oriented population risk analysis, in which the objective is not simply to determine whether one exposure exceeds one threshold, but to understand how changes in formulation, consumption, or policy may alter the overall balance of health impact across the population. That is a more demanding analytical task, but also a more policy-relevant one.

For FSANZ, the value of this extension would be twofold. First, it would strengthen the analytical connection between exposure assessment and risk characterization by making fuller use of available toxicological and epidemiological evidence. Second, it would create a platform for more realistic policy analysis in situations where proposed interventions affect multiple hazards and health determinants simultaneously. In that sense, simulation modelling could become a bridge not only between exposure and risk, but also between risk assessment and risk–benefit assessment.

8.6 Implications for the architecture of future assessment

Taken together, these considerations suggest that the future orientation of risk assessment in this area may need to be tiered and modular. At an early stage, the task is one of problem formulation, screening, and prioritization. At a more advanced stage, where evidence becomes stronger and more coherent, the same framework could support increasingly quantitative forms of analysis, including probabilistic risk characterization and, where appropriate, integrated risk–benefit modelling.

This has an important institutional implication. FSANZ does not need to decide at the outset whether every UPF-related question will ultimately be amenable to full quantitative assessment. What matters is that the framework is built in a way that

allows such progression when justified by the evidence. That would make the system both scientifically disciplined and strategically adaptable.

9. Implications for risk management and monitoring

9.1 Immediate implications

The most immediate implication is not that FSANZ should regulate additive mixtures as if they were newly authorized substances. A more proportionate first step would be to improve post-market intelligence and prioritization.

9.2 Potential monitoring actions

Possible early actions could include:

- mapping additive co-occurrence across major food categories
- identifying recurring additive clusters in high-consumption products
- linking occurrence data to national dietary surveys
- establishing criteria for when specific clusters warrant refined assessment.

9.3 Why post-market surveillance is central

Several sources emphasize that additive-use patterns and food-consumption patterns change over time, which means exposure databases can become outdated relatively quickly (Löwik 1996). EFSA and FACET-related work show the value of surveillance systems that incorporate actual occurrence and concentration variability. For FSANZ, this argues for a more dynamic monitoring architecture.

9.4 A staged governance model

A staged model could be envisaged:

- **Stage 1**: exploratory surveillance and descriptive mapping
- **Stage 2**: focused assessment of recurring mixture profiles or high-priority contexts
- **Stage 3**: consideration of risk management responses where evidence supports additive-related relevance beyond existing controls.

10. Communication considerations

10.1 Core message

Communication should make clear that FSANZ is not presuming that additive mixtures explain UPF-related health effects. Rather, FSANZ is recognizing that:

- real-world additive mixtures exist
- their significance remains scientifically open
- and a modern regulator should be able to examine their relevance within a broader comparative framework.

10.2 Avoiding false binaries

The issue should not be framed as a choice between "the current system is enough" and "the entire system must be redesigned around cocktails." The more credible position is that the existing system remains necessary but may require complementary tools for emerging system-level questions.

11. Discussion

The main lesson of this case study is that the challenge posed by UPFs is, in large part, a challenge of framing. The additive-mixture literature is helpful precisely because it sharpens this point. It does not prove that additives are the answer. What it shows is that additive-related mechanisms are no longer too speculative to consider. Consumers are exposed to additive mixtures in real foods and real diets; co-occurrence patterns are structured; some toxicological and epidemiological findings suggest possible relevance; and regulatory science is beginning to develop the monitoring and assessment tools needed to address such questions more realistically (Chazelas et al. 2020; COT 2009; Payen de La Garanderie et al. 2025; Recoules et al. 2024; Shaw 2014).

At the same time, the literature repeatedly cautions against overreach. The toxicological significance of additive mixtures remains unresolved (Samoylov and Suraeva 2024). No single test battery can capture all mixture-related effects (Thomas and Adegoke 2015). Observational findings remain vulnerable to confounding and misclassification. These limitations do not weaken the case for inquiry. They explain why the inquiry must be structured, comparative, and proportionate.

12. Conclusions

The central lesson of this case study is that the challenge posed by ultra-processed foods (UPFs) is not only a question of evidence, but fundamentally a question of **problem formulation**. The available literature does not support a single, dominant causal explanation. Instead, it points to a set of plausible, potentially interacting mechanisms, including nutrient composition, energy density, food structure and texture, eating rate, hyper-palatability, dietary displacement, broader food-environment drivers, and additive-related factors.

In this context, the primary task for FSANZ is not to select one mechanism prematurely, but to establish a structured, comparative framework capable of identifying which features of UPFs are most plausibly relevant to adverse dietary and

health outcomes, and which of those features are sufficiently evidence-based and governable to justify regulatory attention.

Within this broader framework, additive-related mechanisms should be treated as **credible but not pre-established hypotheses**. The emerging literature on food additive mixtures materially strengthens the rationale for including such mechanisms in the assessment. It shows that:

- real-world exposure to additives occurs as mixtures rather than isolated substances (COT 2009; Shaw 2014)
- additive co-occurrence in foods is common and structured (Chazelas et al. 2020)
- additive mixture profiles can be identified in population-level dietary data (Payen de La Garanderie et al. 2025)
- some toxicological and epidemiological findings raise plausible but unresolved questions about combined effects (Recoules et al. 2024; Samoylov and Suraeva 2024)
- and regulatory science is increasingly capable of supporting mixture-aware exposure monitoring and prioritizations (FACET materials (NAL n.d.); EFSA RACEMiC roadmap (de Jong et al. 2022).

At the same time, the evidence base remains heterogeneous and incomplete. The toxicological significance of additive mixtures is not yet established in a generalizable way, and epidemiological findings remain subject to uncertainty and potential confounding. For this reason, additive-related constructs such as additive load and functional stacking should be used as **analytical tools for prioritizations and hypothesis testing**, rather than as proxies for risk.

A key implication of this case study is that the evolution of risk assessment in this area is likely to be **progressive and tiered**. At an initial stage, the framework supports improved problem formulation, structured comparison of competing hypotheses, and enhanced post-market intelligence. At a more advanced stage, where the evidence base becomes sufficiently robust, the same framework could support **quantitative probabilistic risk characterization**, linking exposure distributions to toxicological or epidemiological response functions under explicit treatment of variability and uncertainty.

Such an approach would allow FSANZ to move beyond descriptive exposure analysis toward estimation of population-level risk distributions, including subgroup differences, high-percentile exposures, and the sensitivity of results to key assumptions. In doing so, probabilistic modelling, including Monte Carlo simulation, would serve not only as a technical refinement, but as a core instrument for improving transparency and decision support.

In addition, the same modelling architecture could provide a basis for more integrated **risk–benefit assessment**, particularly in situations where food reformulation or

policy interventions affect multiple health pathways simultaneously. In the UPF context, this may include trade-offs between nutrient profile, energy density, product structure, additive use, and consumption patterns. A scenario-based approach would make it possible to compare alternative interventions in terms of their net impact on population health, rather than evaluating each component in isolation.

Taken together, these elements point toward a broader shift in food risk analysis: from a system focused primarily on **single-substance hazard assessment** to one increasingly capable of addressing **complex, system-level dietary questions**. This does not diminish the importance of existing additive safety frameworks. Rather, it highlights the need for complementary tools that can operate at the level of dietary patterns, product design, and cumulative exposure.

The appropriate conclusion, therefore, is not that additive mixtures, or any other single feature, constitute the established explanation for UPF-related health effects. It is that FSANZ should adopt a framework that allows such hypotheses to be examined rigorously, comparatively, and proportionately, while maintaining transparency about uncertainty and avoiding premature closure of the causal question.

In that sense, this case study illustrates a more general principle for modern risk governance: when confronted with complex and evolving food-system challenges, the quality of decisions depends critically on the quality of the questions being asked.

References for Case Study 2

Bolhuis D and Forde CG (2020) Application of food texture to moderate oral processing behaviors and energy intake, *Trends in Food Science & Technology*, 106:445–456, doi:10.1016/j.tifs.2020.10.021.

Chazelas E, Deschasaux M, Srour B, Kesse-Guyot, E, Julia, C, Alles, B, Druesne-Pecollo N, Galan P, Hercberg S, Latino-Martel P, Esseddik Y, Szabo F, Slamich P, Gigandet S and Touvier M (2020) Food additives: Distribution and co-occurrence in 126,000 food products of the French market, *Scientific Reports*, 10:3980, doi:10.1038/s41598-020-60948-w.

COT (The Committee on Toxicity) (2008) Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, Statement on Food Standards Agency-funded research on health effects of mixtures of food additives (T01040/41), The Committee on Toxicity, London.
https://cot.food.gov.uk/sites/default/files/cot/cotsection2008.pdf

Demeke S, Rohde K, Chollet-Hinton L, Sutton C, Kong KL and Fazzino TL (2022) Change in hyper-palatable food availability in the US food system over 30 years: 1988–2018, *Public Health Nutrition*, 26(1):182–189, doi:10.1017/S1368980022001227.

Ekenci KD and Köksal E (2024) Dietary exposure assessment to food additives: A critical review of food consumption surveys*, Nutrire*, 49(1):10, doi:10.1186/s41110-024-00252-z.

Ershoff BH (1976) Synergistic toxicity of food additives in rats fed a diet low in dietary fiber, *Journal of Food Science*, 41(4):949–951, doi:10.1111/j.1365-2621.1976.tb00759.x.

de Jong E, van der Voet H, Marx-Stoelting P, Hougaard Bennekou S, Sprong C, Bloch D, Burchardt A, Lasch A, Opialla T, Rotter S, Bay Wedebye E, Zwartsen A, Leys A, Zare Jeddi M, Wolterink G, Kruisselbrink J, de Boer W and van Klaveren J (2022) Roadmap for action on Risk Assessment of Combined Exposure to Multiple Chemicals (RACEMiC), *EFSA Supporting Publications*, 19(10):EN-7555. 197, doi:10.2903/sp.efsa.2022.EN-7555.

EFSA (2026) Food additives, European Food Safety Authority, Parma. https://www.efsa.europa.eu/en/topics/topic/food-additives

Fazzino TL, Rohde K and Sullivan DK (2019) Hyper-palatable foods: Development of a quantitative definition and application to the US food system database, *Obesity*, 27(11):1761–1768, doi:10.1002/oby.22639.

FDA (2026), Food chemical safety, Food and Drug Administration, Silver Spring, MD, United States. https://www.fda.gov/food/food-ingredients-packaging/food-chemical-safety

Forde CG and Bolhuis D (2022) Interrelations between food form, texture, and matrix influence energy intake and metabolic responses, *Current Nutrition Reports*, 11:124–132, doi:10.1007/s13668-022-00413-4.

Forde CG, Heuven LAJ, van Bruinessen M, Liu Z, Stieger M, de Graaf K and Lasschuijt MP (2026) Eating rate has sustained effects on energy intake from ultraprocessed diets: A 2-week ad libitum dietary randomized controlled crossover trial, *The American Journal of Clinical Nutrition*, 123(4):101122, doi:10.1016/j.ajcnut.2025.11.012.

Jun D, Knowles K and Fazzino T (2025) Examination of hyper-palatable foods and their nutrient characteristics using globally crowdsourced data, *PLOS ONE*, 20(6):e0325479. doi:10.1371/journal.pone.0325479.

Lasschuijt M, Camps G, Mars M, Siebelink E, de Graaf, K and Bolhuis D (2023) Speed limits: The effects of industrial food processing and food texture on daily energy intake and eating behaviour in healthy adults, *European Journal of Nutrition*, 62:2949–2962, doi:10.1007/s00394-023-03202-z.

Lee G, Lim HS, Yun SS, Shin JW and Kim M (2019) Safety assessment of antioxidants and color fixatives for the Korean population using dietary intake

monitoring, *Food Additives & Contaminants: Part A*, 36(6):876–883, doi:10.1080/19440049.2019.1595172.

Löwik MRH (1996) Possible use of food consumption surveys to estimate exposure to additives *Food Additives and Contaminants*, 13(4):427–441, doi:10.1080/02652039609374428.

Payen de La Garanderie M, Hasenbohler A, Dechamp N, Javaux G, Szabo de Edelenyi F, Agaësse C, De Sa A, Bourhis L, Porcher R, Pierre F, Coumoul X, Kesse-Guyot, E, Allès B, Fezeu L K, Cosson E, Tatulashvili S, Huybrechts I, Hercberg S, Deschasaux-Tanguy M, Chassaing B, Rytter H, Srour B and Touvier M (2025) Food additive mixtures and type 2 diabetes incidence: Results from the NutriNet-Santé prospective cohort*, PLOS Medicine*, 22(4):e1004570, doi:10.1371/journal.pmed.1004570.

Payen de La Garanderie M, Dechamp N, Verdot C, Hasenbohler A, Yvroud-Hoyos P, Szabo de Edelenyi F, Agaësse C, De Sa A, Kesse-Guyot E, Allès B, Deschasaux-Tanguy M, Huybrechts I, Pierre F, Audebert M, Coumoul X, Srour B, Deschamps V and Touvier M (2025) Food additive mixtures in French children and adults: The nationally representative Esteban study, *Scientific Reports*, 15:44173, doi:10.1038/s41598-025-27819-8.

Radwan E, Elghazaly MM, Hussein HK, Abdel Aziz KK and Barakat AI (2020) Adverse effect of mixture of food additives on some biochemical parameters in male albino rats, *Journal of Advances in Biology,* 13, doi:10.24297/jab.v13i.8555.

Recoules C, Touvier M, Pierre F and Audebert M (2025) Evaluation of the toxic effects of food additives, alone or in mixture, in four human cell models, *Food and Chemical Toxicology*, 196:115198, doi:10.1016/j.fct.2024.115198.

Rolls BJ, Cunningham PM and Diktas HE (2020) Properties of ultraprocessed foods that can drive excess intake, *Nutrition Today*, 55(3):109–115, doi:10.1097/NT.0000000000000410.

Sado I (1973) Synergistic toxicity of official permissible preservative food additives, *Japanese Journal of Hygiene*, 28(5):463–476, doi:10.1265/jjh.28.463.

Salih FM (2006) Risk assessment of combined photogenotoxic effects of sunlight and food additives, *Science of the Total Environment*, 362(1–3):68–73, doi:10.1016/j.scitotenv.2005.05.027.

Samoylov AV and Suraeva NM (2024) Safety aspects of food additive mixtures, *Food Processing Industry*, 8:15–19, doi:10.52653/PPI.2024.8.8.002.

Shaw IC (2014) Chemical residues, food additives and natural toxicants in food: The cocktail effect, *International Journal of Food Science & Technology*, 49(10):2149–2157, doi:10.1111/ijfs.12606.

Thomas OE and Adegoke OA (2015) Toxicity of food colours and additives: A review, *African Journal of Pharmacy and Pharmacology*, 9(36):900–914, doi:10.5897/AJPP2015.4385.

NAL (National Agricultural Library) (n.d.) FACET: Flavourings, Additives and Food Contact Material Exposure Task. Food Safety Research Projects Database, Maryland, United States. https://www.nal.usda.gov/research-tools/food-safety-research-projects/facet-flavourings-additives-and-food-contact-material

Vin K, Connolly A, McCaffrey T, McKevitt A, O'Mahony C, Prieto M, Tennant D, Hearty Á and Volatier JL (2013) Estimation of the dietary intake of 13 priority additives in France, Italy, the UK and Ireland as part of the FACET project, *Food Additives & Contaminants: Part A*, 30(12):2050–2080, doi:10.1080/19440049.2013.851417.

Case Study 3. D-Allulose (A1247): An Integrated Risk Assessment and Risk Governance Perspective for Novel Food Approval

Executive summary

This case study examines the approval of D-allulose (Application A1247) to illustrate how FSANZ's established novel food assessment framework can be extended toward a more **integrated, decision-oriented approach** that explicitly incorporates safety, nutrition, dietary patterns, and public-health considerations.

FSANZ completed its evaluation in 2024 and determined that D-allulose does not pose a toxicological concern under the proposed conditions of use. The critical endpoint identified was gastrointestinal tolerance at high intakes, consistent with the known behavior of low-digestibility carbohydrates (FSANZ 2024a). The resulting regulatory package was proportionate and coherent, combining maximum permitted levels by food category, mandatory laxative advisory statements for high-dose products, and updates to nutrition labelling, including the assignment of an energy factor of 2 kJ/g and exclusion of D-allulose from "sugars" in nutrition information panels (FSANZ 2024a).

While this assessment robustly addressed safety and key nutritional parameters, the case study highlights an additional dimension: the system-level impact of such an ingredient on dietary patterns and public-health outcomes. FSANZ noted that D-allulose was approved across 18 food categories, the majority of which fall within discretionary foods or "foods to limit" under the Australian Dietary Guidelines (FSANZ 2024a; NHMRC 2013). Many of these products remain high in fat and/or sodium and provide limited nutritional value.

This raises a strategic question for risk governance. While D-allulose may reduce sugar content, could its use in such products unintentionally reinforce consumption of discretionary foods? Submissions to FSANZ highlighted the potential for a "halo effect," whereby consumers perceive reformulated products as healthier and increase their intake accordingly (Chandon and Wansink 2006; FSANZ 2024a).

The case study therefore reframes the assessment around a broader regulatory question:

How can FSANZ ensure that the approval and conditions of use of D-allulose contribute to reducing added sugar exposure, while maintaining safety and supporting coherent public-health nutrition outcomes?

To address this, the case study develops an integrated analytical approach combining toxicological assessment, dietary exposure modelling, behavioural considerations, and—where feasible—**probabilistic and risk–benefit modelling frameworks** (FAO and WHO 2009).

1. Introduction

1.1 Public-health context

Excess intake of added sugars has been consistently associated with obesity, type 2 diabetes, and cardiovascular disease (Te Morenga et al. 2013; WHO 2015). As a result, many jurisdictions have prioritized sugar reduction as a key public-health objective.

Low-energy sweeteners, including rare sugars such as D-allulose, are increasingly considered as technological tools to support this objective (Mooradian et al. 2017). D-allulose provides approximately 70% of the sweetness of sucrose with minimal caloric contribution and a limited glycaemic response (Hayashi et al. 2010; Iida et al. 2008; Iida et al. 2010).

1.2 Limits of traditional assessment

Traditional novel food assessment frameworks, as applied by FSANZ, Codex, EFSA, and FDA, are primarily designed to establish **toxicological safety** (Codex 2003; Codex 2007; EFSA 2016; FDA 2020). While this remains essential, it does not fully capture the broader implications of ingredients intended to modify dietary behavior.

This has led to increasing recognition that food risk assessment may need to incorporate **nutrition and dietary-pattern considerations** (EFSA Scientific Committee 2010; EFSA Scientific Committee 2018; GBD 2017 Diet Collaborators 2019).

2. Global regulatory trajectory of D-allulose

The regulatory treatment of D-allulose illustrates differences in evidentiary thresholds and governance approaches.

FSANZ concluded that D-allulose is safe under proposed conditions of use (FSANZ 2024b). The U.S. Food and Drug Administration similarly recognised D-allulose as safe under GRAS notifications and excluded it from added sugars labelling (FDA 2024).

In contrast, the European Food Safety Authority determined that safety could not be established due to data gaps, including lack of long-term toxicity and human exposure data (EFSA 2025).

Such divergence reflects differences in application of the precautionary principle rather than conflicting core evidence (van der Sluijs et al. 2005).

3. Reframing the problem

3.1 From ingredient safety to dietary impact

While D-allulose is safe, its **public-health relevance depends on its role within the diet**. This reflects a broader shift from nutrient-based to pattern-based approaches in nutrition science (Mozaffarian et al. 2018).

3.2 Dietary-pattern considerations

Dietary guidelines emphasize whole dietary patterns rather than single nutrients (NHMRC 2013). Interventions targeting discretionary foods may have limited impact if overall consumption patterns remain unchanged.

3.3 Behavioral effects

Consumer perception influences dietary outcomes. The "halo effect" can lead to increased consumption of products perceived as healthier (Chandon and Wansink 2007; Sütterlin and Siegrist 2015).

4. Problem formulation

4.1 Core question

How can FSANZ ensure that D-allulose use achieves sugar reduction objectives while maintaining safety and supporting healthy dietary patterns?

4.2 Secondary question

Secondary questions might include, for example:

- Under which conditions of use does D-allulose result in meaningful reductions in added sugar intake at the population level?
- Which food categories dominate dietary exposure and potential consumption shifts?
- How do gastrointestinal tolerance limits constrain realistic intake scenarios?
- Could use of D-allulose contribute to unintended dietary pattern effects, including increased consumption of discretionary foods?
- Which risk management measures best support safe use while avoiding misleading health perceptions?

4.3 Analytical implications

This requires integrating:

- toxicological safety
- exposure assessment
- dietary modelling
- behavioral considerations
- uncertainty analysis

5. Evidence integration

5.1 Evidence streams

Evidence includes:

- toxicological data (GI tolerance)
- metabolic studies (glycaemic response)
- dietary surveys (ABS 2014)
- product composition data
- behavioral evidence

5.2 Integration challenge

Part of the problem presented here is the integration of various elements of science. Again, from a nutrition perspective, the evidence against sugar (and fat) in the diet largely emerged from epidemiological studies where these two dietary components emerged as indicative parameters of poor dietary patterns. This means that just attending to the sugar content of a food will not necessarily address the problem of food quality and overall healthy diets (GBD 2017 Diet Collaborators 2019). Looking at another way, sugar could be a marker of an unhealthy dietary pattern, so what is the benefit of sugar replacements in otherwise poor-quality foods?

FSANZ's assessment of D-allulose covers major traditional nutritional aspects, such as estimating energy value, considering glycaemic effects, and updating labeling rules. An integrated approach would formalize this by weighing the nutritional benefits against the safety side-by-side. In practical terms, this might involve assessing how replacing sucrose with D-allulose changes daily sugar and energy intakes at a population level. Another important aspect to consider would be weighing these potential benefits against what is already known about GI tolerance thresholds.

Making sure that nutrition specialists and toxicologists together read and understand information about glycaemic response, dental health, and metabolic impacts does not change the separate safety conclusion already made by FSANZ but rather puts it into a wider public-health narrative. This in turn assists the communication of how the approved maximum use levels and warning statements form a coherent package of proportionate and protective measures.

6. Application of the risk assessment framework

6.1.Hazard Identification

Classical scope: Identification of adverse health effects associated with D-allulose consumption, with gastrointestinal effects at high intakes identified as the critical effect.

Extended consideration: identification of system-level considerations relevant to public health, including:

- Predominant use in discretionary foods
- Potential for altered consumption patterns
- Interaction with existing dietary risk factors (e.g. high fat and sodium intake)

6.2. Hazard Characterization

Classical scope: characterization of dose–response relationships for gastrointestinal tolerance and derivation of safe intake thresholds.

Extended characterization (fit-for-purpose), includes parallel consideration of:

- The plausibility and magnitude of nutritional benefit (added sugar reduction)
- Constraints imposed by tolerance thresholds
- Explicit characterization of uncertainties related to long-term dietary effects

Toxicological safety conclusions remain distinct and unchanged, while additional dimensions are transparently documented.

6.3. Exposure Assessment

Classical scope: estimation of dietary exposure to D-allulose under proposed conditions of use, compared with tolerance thresholds.

Diet- and pattern-aware extension includes:

- Scenario-based dietary exposure modelling
- Assessment of contribution to total added sugar intake
- Identification of population subgroups with higher exposure
- Consideration of substitution versus compensation effects

6.4. Risk Characterization

Classical scope: conclusion that D-allulose does not present a safety concern under defined conditions of use.

Decision-ready characterization: integrated synthesis describing:

- Where safety margins are robust
- Where nutritional benefit is plausible, limited, or uncertain
- Which food categories are priority contexts for risk management
- Key sources of uncertainty relevant to decision-making

7. Toward probabilistic and integrated assessment

Where evidence permits, exposure distributions could be linked to:

- GI tolerance dose–response models
- epidemiological models linking sugar intake to disease outcomes (WHO 2015; Te Morenga et al. 2013)

Monte Carlo simulation can:

- represent variability
- propagate uncertainty
- support scenario comparison (Vose 2008)

8. Risk–benefit perspective

Risk–benefit frameworks are increasingly recognised in food regulation (EFSA 2010).

D-allulose illustrates trade-offs between:

- reduced sugar intake (benefit)
- GI tolerance and behavioral effects (risk)

9. Risk communication and management interface

Risk communication is treated as a **continuous process**, including:

- Clear articulation of what the assessment does and does not conclude
- Explicit explanation that approval does not constitute a nutritional endorsement
- Plain-language communication of uncertainty and conditions of use

Consistent with Codex guidance, risk management options are considered separately from the risk assessment, informed by its conclusions.

Illustrative measures include:

- Category-specific maximum use levels
- Mandatory advisory statements for high-dose products
- Nutrition labelling provisions excluding D-allulose from "sugars"

- Consideration of post-market monitoring and review

These measures support proportionate risk management without undermining innovation.

10. Reflections and transferability

Integrated approaches align with modern risk governance frameworks (IRGC 2017; OECD 2014), emphasizing transparency, stakeholder engagement, and adaptability.

This case study illustrates how FSANZ novel food assessments can remain fully aligned with Codex principles while strengthening their relevance to public-health nutrition objectives, transparency, and modern risk governance.

FSANZ has in practice submitted to transparency and stakeholder consultation, documented by detailed public records and open calls for comment as part of demonstrating modern risk-governance principles. Integration would strengthen these attributes and provide the opportunity to enhance them by, for example, sharing methodological elements (e.g., intake modelling assumptions) earlier in the process where feasible and broadening stakeholder engagement to include clinical and public health organizations given the relevance of D-allulose for diets high in added sugars.

The addition of post-market surveillance or a scheduled review of emerging science would provide an approach that supports precaution but does not constrain innovation. Such enhancements would not signal uncertainty in the current scientific conclusion but, rather, demonstrate FSANZ's commitment to adaptive, evidence-informed governance and appropriate regulatory oversight of novel ingredients entering the food system at scale.

Combined, these possibilities develop FSANZ's strength and put its novel food assessments at the forefront of integrated public health-oriented food regulation. The outcome is a regulatory process that continuously remains scientifically rigorous while at the same time responsive to evolving nutrition priorities and consumer expectations.

Conclusion

D-allulose demonstrates that modern food regulation must move beyond safety alone toward integrated, system-level assessment. This aligns with evolving international approaches combining toxicology, nutrition, and public health.

References for Case Study 3

ABS (2014) Australian Health Survey: Nutrition First Results – Foods and Nutrients (Reference period 2011–12 financial year), Australian Bureau of Statistics, Canberra. https://www.abs.gov.au/Ausstats/abs@.nsf/mf/4364.0.55.007.

Chandon P and Wansink B (2007) The biasing health halos of fast-food restaurant health claims: Lower calorie estimates and higher side-dish consumption intentions, *Journal of Consumer Research*, 34(3):301–314, doi:10.1086/519499.

Codex Alimentarius Commission (2003) Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, in *Codex Alimentarius Commission Procedural Manual,* Codex Alimentarius Commission, Rome. https://www.fao.org/4/y5817e/y5817e04.htm.

Codex Alimentarius Commission (2007) Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007), Codex Alimentarius Commission, Rome. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B62-2007%252FCXG_062e.pdf.

EFSA Scientific Committee (2010) Guidance on human health risk-benefit assessment of foods, *EFSA Journal*, 8(7):1673, doi:10.2903/j.efsa.2010.1673.

EFSA Scientific Committee (2018) Guidance on uncertainty analysis in scientific assessments, *EFSA Journal*, 16(1):5123, doi:10.2903/j.efsa.2018.5123.

EFSA (2016) Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 *EFSA Journal*, 14(11):4594, doi:10.2903/j.efsa.2016.4594.

EFSA (2025) Safety of D-allulose as a novel food pursuant to Regulation (EU) 2015/2283, *EFSA Journal*, 23(6):e9468, doi:10.2903/j.efsa.2025.9468.

FAO and WHO (2009) Principles and methods for the risk assessment of chemicals in food. Environmental Health Criteria 240, World Health Organization, Geneva. https://www.who.int/publications/i/item/9789241572408.

FDA (2020) Guidance for Industry: The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels. U.S, *Food and Drug Administration*. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-declaration-allulose-and-calories-allulose-nutrition-and-supplement-facts-labels.

FDA (2024a) Agency Response Letter GRAS Notice No. GRN 001148 U.S, *Food and Drug Administration*. https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?id=1148&set=GRASNotices.

FDA (2024b) Agency Response Letter GRAS Notice No. GRN 001193. U.S, *Food and Drug Administration*. https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?id=1193&set=GRASNotices.

Food Standards Australia New Zealand (2024a) Application A1247: D-allulose as a novel food, Approval Report, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/2024-08/A1247%20Approval%20Report.pdf.

FSANZ (2024b) Application A1247: D-allulose as a novel food, Supporting Document 1 at Approval, Food Standards Australia New Zealand, Canberra. https://www.foodstandards.gov.au/sites/default/files/2024-08/A1247_SD1_at_Approval.pdf.

GBD 2017 Diet Collaborators (2019) Health effects of dietary risks in 195 countries, 1990–2017: A systematic analysis for the Global Burden of Disease Study 2017, *The Lancet*, 393(10184):1958–1972, doi:10.1016/S0140-6736(19)30041-8.

Hayashi N, Iida T, Yamada T, Okuma K, Takehara I, Yamamoto T, Yamada, K and Tokuda M (2010) Study on the postprandial blood glucose suppression effect of D-psicose in borderline diabetes and the safety of long-term ingestion by normal human subjects, *Bioscience, Biotechnology, and Biochemistry*, 74(3):510–519, doi:10.1271/bbb.90707.

Iida T, Kishimoto Y, Yoshikawa Y, Hayashi N, Okuma K, Tohi M, Yagi K, Matsuo T and Izumori K (2008) Acute D-psicose administration decreases the glycemic responses to an oral maltodextrin tolerance test in normal adults, *Journal of Nutritional Science and Vitaminology*, 54(6):511–514, doi:10.3177/jnsv.54.511.

Iida T, Hayashi N, Yamada T, Yoshikawa Y, Miyazato S, Kishimoto Y, Okuma K., Tokuda M and Izumori K (2010) Failure of D-psicose absorbed in the small intestine to metabolize into energy and its low large intestinal fermentability in humans, *Metabolism*, 59(2):206–214, doi:10.1016/j.metabol.2009.07.018.

IRGC (International Risk Governance Council) (2017) Introduction to the IRGC Risk Governance Framework: Revised Version. EPFL International Risk Governance Center, Lausanne. https://irgc.org/wp-content/uploads/2018/09/IRGC.-2017.-An-introduction-to-the-IRGC-Risk-Governance-Framework.-Revised-version..pdf

Mooradian A D, Smith M and Tokuda M (2017) The role of artificial and natural sweeteners in reducing the consumption of table sugar: A narrative review, *Clinical Nutrition ESPEN*, 18:1–8, doi:10.1016/j.clnesp.2017.01.004.

Mozaffarian D, Rosenberg I and Uauy R (2018) History of modern nutrition science: Implications for current research, dietary guidelines, and food policy, *BMJ*, 361:k2392, doi:10.1136/bmj.k2392.

NHMRC (2013) Australian Dietary Guidelines. National Health and Medical Research Council, Canberra. https://www.nhmrc.gov.au/adg.

OECD (2014) Recommendation of the Council on the Governance of Critical Risks. Organisation for Economic Co-operation and Development, Paris. https://www.oecd.org/gov/risk/recommendation-on-governance-of-critical-risks.htm

Sütterlin B and Siegrist M (2015) Simply adding the word "fruit" makes sugar healthier: The misleading effect of symbolic information on the perceived healthiness of food, *Appetite*, 95:252–261, doi:10.1016/j.appet.2015.07.011.

Te Morenga L, Mallard S and Mann J (2013) Dietary sugars and body weight: Systematic review and meta-analyses of randomised controlled trials and cohort studies, *BMJ*, 346: e7492, doi:10.1136/bmj.e7492.

van der Sluijs JP, Kaiser M, Beder S, Hösle V, Kemelmajer de Carlucci A and Kinzig A (2005) The Precautionary Principle, UNESCO, Paris. https://dspace.library.uu.nl/handle/1874/20676

Vose D (2008) Risk Analysis: A Quantitative Guide (3rd ed.) John Wiley & Sons.

WHO (2015) Guideline: Sugars intake for adults and children, World Health Organization, Geneva. https://www.who.int/publications/i/item/9789241549028

GLOSSARY

Commodity foods: raw unprocessed agricultural products, generally traded in bulk

Contingent (or scenario-based) risk assessment: indicates the likely effectiveness of a range of policy interventions or other regulatory measures by estimating how residual risk would change under alternative interventions, both alone and in combination.

Core food groups: groups of nutritious foods that go to make up the Australian Guide to Healthy Eating (https://www.eatforhealth.gov.au/food-essentials/five-food-groups)

Dietary Guidelines: refers collectively to the documents: Australian Dietary Guidelines, Australian Infant Feeding Guidelines, New Zealand Eating and Activity Guidelines and New Zealand Food and Nutrition Guidelines for other specified age and stage groups.

Dietary pattern: is the habitual way in which an individual or a population consumes food and beverages over time. This definition encompasses the types of foods, their proportions, variety, frequency, and combinations in the diet. It moves beyond simple food lists to encompass the complex interplay of food choices and eating behaviors to provide a holistic view that in turn informs an understanding of the impact of diet on health.[1]

Discretionary foods: include sweet biscuits, cakes, desserts and pastries; processed meats and fattier/salty sausages; sweetened condensed milk; ice cream and other ice confections; confectionary and chocolate; savoury pastries and pies; commercial burgers with a high fat and/or salt content; commercially fried foods; potato chips, crisps and other fatty and/or salty snack foods including some savoury biscuits; cream, butter and spreads which are high in saturated fats; sugar-sweetened soft drinks and cordials, sports and energy drinks and alcoholic drinks.[2]

Food Ministers: collectively, the lead Ministers for health and food safety from each Australian State and Territory and from the Australian and New Zealand Governments.

Food formulation: refers to the recipe of ingredients and general design of individual foods (IFT)

Food processing : includes freezing, canning, drying, preserving, fermentation, with other techniques including the use of additives and preservatives, high pressure cooking, frying, dehydration, purification, heat treating and chemical modification (FSANZ)

Food Standards Code: is a comprehensive framework developed by FSANZ that sets out the legal requirements for food products manufactured, sold or imported into Australia and New Zealand.

Health-based guidance values: (e.g. dietary reference values in the case of nutrients, or acceptable daily intakes in the case of food additives)

National dietary surveys: collect information about nutritional intakes, including foods, nutrients and supplements consumed, typically using a variety of dietary recall and self-reported questionnaire methodologies. They aim to generate comprehensive and nationally representative data on, and to support analysis of, dietary intakes, behaviours and dietary patterns.

Non-communicable diseases (NCDs): are chronic health conditions that result from a combination of genetic, lifestyle and environmental factors.[3]

Novel foods: Non-traditional foods that require assessment by FSANZ to establish their safety before they are added to the food supply. (FSANZ)

Nutrient based food categorisation: classification of foods based on their relative nutrient content/value with reference to key nutrients such as protein, carbohydrate and fat, and then individual vitamins and minerals

Nutrition risk assessment: assessment of the potential risk of a nutrient, food, property of food or substance added to food in terms of (a) risk of deficiency or excess of nutrients (FSANZ) and (b) risk of enabling dietary patterns associated with non-communicable disease (panel)

Plant-based alternatives to cows' milk: beverages derived from cereals (eg rice, oats), legumes (eg soy) or nuts (eg almond) or combinations thereof, as dairy milk alternatives

Process-based food categorisation: classification of foods based on their transformation from agricultural [plant and animal] products using a range of techniques and methods into food ingredients or products (IFT)

Risk nutrients: refers to nutrients provided in excess and associated with poor eating habits and/or higher risk of NCDs, nominally sodium, (saturated fats, trans) and sugar (FSANZ)

Ultra-processed foods: foods which are formulations of ingredients, mostly of exclusive industrial use, typically created by a series of industrial techniques and processes (NOVA classification)

ACKNOWLEDGEMENTS

The panel is grateful to Glenys Beauchamp AO and Robyn Kruk AO, respectively Chairperson and Acting Chairperson of the FSANZ Board, Dr Sandy Cuthbert, Chief Executive Officer of FSANZ and their FSANZ Board and Executive colleagues for their open engagement and discussion. The panel is particularly grateful to Christel Leemhuis, Xenia Papayianis and Emma Breen for their support, guidance and expert project management throughout the eight months of the panel's work, and to Dr Maddy Hunter and Jana Ainkaran for their support in formatting this final report and collating references.

The panel would like to give its special thanks to colleagues in other food and public health organizations who contributed their knowledge and expertise in the preparation of the chapter of the report on global best practices:

- Dr Alfred Aziz (Director, Bureau of Nutritional Science), Jennifer Barber (Acting Chief, Nutrition Pre-Market Assessment Division), Ramandeep Randhawa (Acting Manager in Nutrition Pre-market Assessment Division) and Bryony Sinclair (Manager, Evidence Review for Dietary Guidance, Bureau of Healthy Eating Policy and Promotion) of Health Canada
- Dr Rachel Allen (SACN Team Leader) of the UK Department of Health and Social Care
- Agnes de Sesmaisons Lecarré and Silvia Valtueña Martínez, Senior Scientific Officers of the European Food Safety Authority
- Dr Clare O'Donovan, Niamh Clarke, Susan Parkinson, Aisling Dunphy, Dr Claire Erraught and Patrick John O'Mahony of the Food Safety Authority of Ireland
- Dr Jason Montez and Dr Rain Yamamoto of the World Health Organization