FOOD STANDARDS
Australia • New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes

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- Ms Janis Baines, Australian Bureau of Statistics
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Foreword

As the General Manager, Science and Risk Assessment at FSANZ, I am pleased to present the second edition of the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes.

Dietary exposure assessment is a key step in risk analysis for food regulation. FSANZ applies international best practice to estimate dietary exposure to, or intake of, a range of food chemicals proposed or currently in a wide variety of foods and food groups consumed across Australia and New Zealand. FSANZ's dietary exposure and intake assessments are then used to inform risk management and risk communication both domestically and internationally.

FSANZ's expertise in dietary exposure assessment is recognised globally. FSANZ continues to provide technical input into two independent scientific expert committees which provide risk assessment advice to Codex, the Food and Agriculture Organization (FAO), and the World Health Organization (WHO) and their member states and input into international publications.

The first edition of the Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes was published 15 years ago. In that time, new data and updated methodologies have been incorporated into how dietary exposure assessments are conducted at FSANZ. These changes are reflected in this revised edition. FSANZ will continue to integrate new data and emerging knowledge and innovative dietary exposure techniques into its assessments; thereby upholding FSANZ's vision of *World-leading standards, safe food for life*.

Christel Leemhuis
General Manager, Science and Risk Assessment
Food Standards Australia New Zealand
December 2024

1 INTRODUCTION

1.1 Purpose and outline of this document

FSANZ aims for transparency when conducting risk assessments for food regulatory and related purposes, including dietary exposure assessments for Australian and New Zealand populations.

The purpose of this document is to:

- identify the principles that Food Standards Australia New Zealand (FSANZ) follows when conducting dietary exposure assessments
- provide a broad overview of the process of estimating dietary exposure to food chemicals
- explain how FSANZ uses information, including that submitted by stakeholders for the purposes of estimating dietary exposure.

This document is a living one and cannot include all relevant material in a rapidly developing area of regulatory science. It is anticipated that the document will be updated regularly to incorporate major changes in principles and practices. For all enquiries in relation to dietary exposure assessment at FSANZ, a general enquiry can be submitted at https://www.foodstandards.gov.au/contact.

1.1.1 Key changes since the first edition

This document is the second edition of the *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes*. Since the first edition was published in 2009, updated data, guidance materials and computer software programs have become available for use in dietary exposure assessments at FSANZ. These include:

- data from more recent Australian and New Zealand national nutrition surveys
- an update of *Chapter 6 Dietary Exposure Assessment for Chemicals in Food* of *EHC (Environmental Health Criteria) 240* (FAO/WHO 2020a)
- the development and use of FSANZ's second custom built computer application for dietary exposure assessment - *Harvest* (replacing DIAMOND[1]). Detailed information about Harvest can be found in section 5.13 and on the FSANZ website (FSANZ 2023i).

As a result, key changes to the second edition of this document include:

- inclusion of data from the 2011-13 Australian Health Survey (ABS 2014b) and the 2008/09 New Zealand Adult Nutrition Survey (University of Otago and Ministry of Health 2011)
- updated and new dietary exposure assessment methodologies
- information on the use of *Harvest* for dietary exposure assessments at FSANZ.

[1] DIAMOND was FSANZ's original custom-built dietary modelling program that completed the same calculations as *Harvest* using a different software program.

1.2 What is dietary exposure assessment?

Exposure assessments provide an estimate of the magnitude, frequency and duration of exposure to risk factors found in the environment. Dietary exposure assessments can be defined as the qualitative and/or quantitative evaluation of the likely intake of chemicals via food, beverages, drinking water and dietary supplements (FAO/WHO 2020a). Dietary exposure assessments draw on food chemical concentration and food consumption[2] data from a range of sources, which are described in Chapter 4 of this document. The specific practices used for dietary exposure assessments for different types of food chemicals are described in Chapters 5 and 6.

In this document food chemical refers to food additives, contaminants, natural toxicants, agricultural and veterinary (agvet) chemical residues, nutrients, nutritive substances, novel foods[3], processing aids, packaging migrants and other food chemicals (e.g. caffeine). Food chemical also refers to metabolites, toxins or any other active substance naturally occurring or present in food. Food chemical does not include genetically modified food, irradiation or microorganisms, however this document does include information on the practices required for dietary exposure assessments for genetically modified food, for foods treated with irradiation, and for risk assessment of both pathogenic and beneficial microorganisms. For nutrients and nutritive substances, the estimated dietary exposure is by convention often referred to as the nutrient or nutritive substance intake, rather than dietary exposure.

2 In this document, 'food' and 'foods' include all foods and beverages consumed by humans.
3 Novel foods are non-traditional foods or ingredients that require an assessment of public health and safety by FSANZ before being permitted for use and added to the food supply.

2 RISK ASSESSMENT AND DIETARY EXPOSURE ASSESSMENT AT FSANZ

2.1 What is FSANZ?

FSANZ is a bi-national independent statutory agency established by the *Food Standards Australia New Zealand Act 1991* (Australian Government 2018). Working within an integrated food regulatory system involving the governments of the States and Territories of Australia and the New Zealand Government, FSANZ sets food standards for the two countries.

FSANZ's mission is to develop world leading food standards for Australia and New Zealand that enable a wide variety of safe foods to be available to consumers. FSANZ develops food standards and joint codes of practice with industry, covering the content and labelling of food sold in Australia and New Zealand. In addition, FSANZ develops Australia-only food standards that address food safety issues, including requirements for primary production of food, and maximum residue limits (MRLs) for agvet chemical residues.

In meeting its statutory obligations, FSANZ considers it is important to document the principles and procedures used in making regulatory decisions, ensuring that a scientific approach is applied to the process of assessing and managing risks associated with proposed changes to the food supply.

2.2 The FSANZ risk analysis framework

FSANZ uses a risk analysis framework to:

- develop new food standards
- evaluate proposed changes to existing food standards
- evaluate existing food standards
- evaluate food technology practices
- address questions about food safety
- consider emerging food safety issues (FSANZ 2013a).

The FSANZ risk analysis framework is based on the Codex Alimentarius Commission (Codex)[4] risk analysis framework (FAO/WHO 2006) and is consistent with those of other international food regulatory and standard setting agencies.

The three parts of risk analysis at FSANZ are:

- risk assessment
- risk management
- risk communication (FSANZ 2013a).

The three parts work in practice in an integrated way as shown in Figure 1.

[4] Codex is the international food standards setting body established by the United Nation's Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

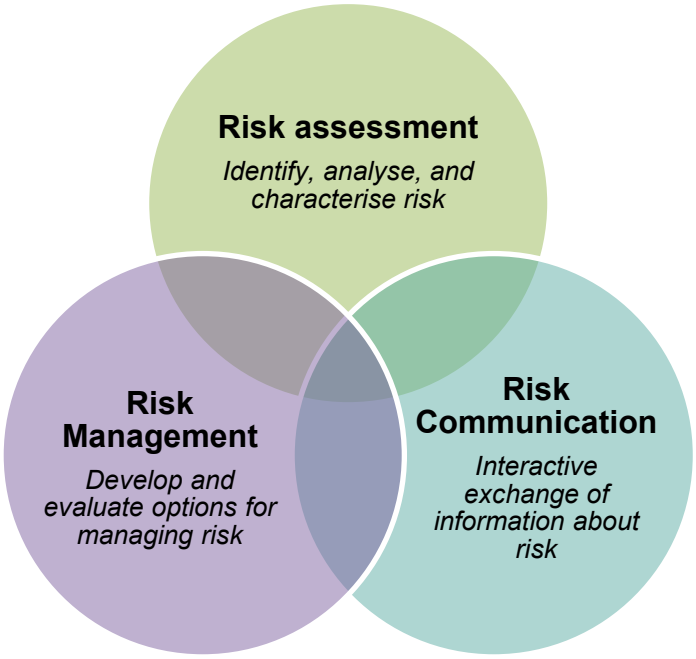

Figure 1: The risk analysis framework (FSANZ 2013a), adapted from FAO/WHO (2006)

Further information on risk assessment, risk management and risk communication at FSANZ can be found in *Risk Analysis in Food Regulation* (FSANZ 2013a).

2.2.1 Risk assessment at FSANZ

Risk assessment at FSANZ follows the model for risk assessment developed by an earlier *Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues* (FAO/WHO 1995). The model consists of four components (see Figure 2):

- hazard identification
- hazard characterisation
- exposure assessment
- risk characterisation.

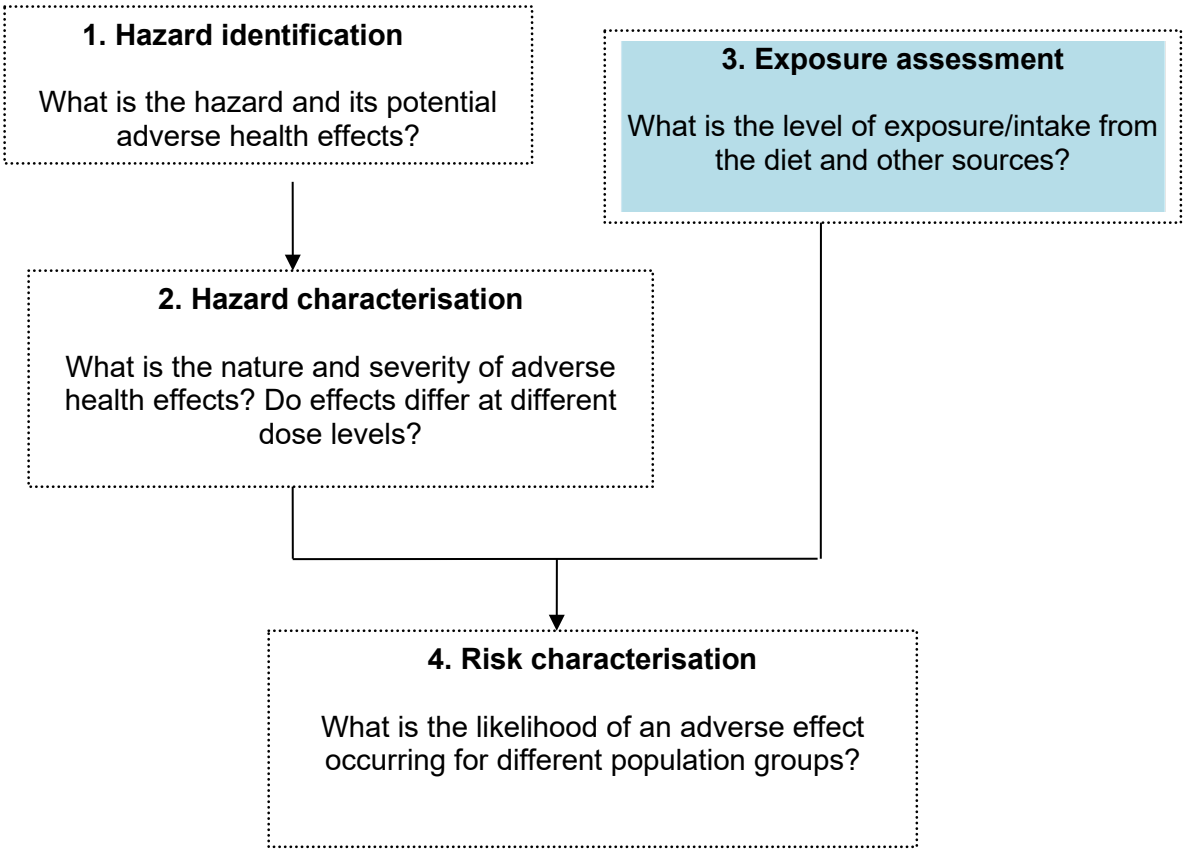

Figure 2: The four steps in risk assessment at FSANZ

2.3 How FSANZ uses dietary exposure assessments

Dietary exposure assessments are part of the FSANZ scientific risk assessment process and are used as a tool for decision-making. They provide a guide to the possible impact of different exposure scenarios or risk management options concerning food chemicals on the Australian and New Zealand populations. Consideration of regulatory options and regulatory decisions are not, and should not be, wholly based on dietary exposure assessments. Many other issues are considered in the risk management process when making regulatory decisions, including technological and economic issues and regulatory impact analysis, see *Risk Analysis in Food Regulation* (FSANZ 2013a).

Within the broader framework of risk assessment, dietary exposure assessments may be used in different ways, including to:

- predict dietary exposure to chemicals in food
- predict risks associated with chemicals in food
- estimate the public health impact of adding a nutritive substance or changing the nutrient content of foods by voluntary or mandatory fortification measures, or by genetic modification.

The major use of dietary exposure assessments at FSANZ is in food standards setting, as

part of the assessment of Applications[5] and Proposals[6]. These purposes can result in changes to the Australia New Zealand Food Standards Code ('the Code') legislation (FSANZ 2023h). For example, dietary exposure assessments are used where required to assess the impact of permitting new food chemicals or extending permissions for food chemicals already in use. Dietary exposure assessments can also be used to characterise changes in the food chemical composition of the food supply and in food consumption patterns, to evaluate the public health impact of food standards over time.

There are many other areas of work at FSANZ that use dietary exposure assessments. Dietary exposure assessments are used in a number of surveillance related activities where chemical concentration data are collected for ongoing or ad hoc surveys. This work includes the Australian Total Diet Study (ATDS) conducted on an ongoing basis for a range of different food chemicals such as pesticide residues, contaminants, natural toxicants, food additives and nutrients. Ad hoc surveillance activities can include collecting data on emerging issues identified internationally for which no, or limited, Australian or New Zealand data are available, or monitoring for chemicals for which the potential risk to the population needs to be assessed or re-evaluated. The concentration data from such surveys are used in dietary exposure assessments to assist in determining the level of risk.

Dietary exposure assessments have been used in considering food recalls to determine whether the level of a chemical in a food posed an unacceptable risk to public health and safety and therefore a food recall was warranted.

For some FSANZ risk assessments, information on the consumption of foods is required. FSANZ's dietary exposure assessment computer application enables food consumption data to be derived for any combination of foods at different levels of specificity for relevant projects. Summary food consumption statistics can be derived as required for specific assessments. This information has been used in assessments for microbiological hazards and genetically modified foods for example, imported food risk advice, or to assist in interpreting dietary exposure assessment results.

In relation to other risk management and risk communication activities, dietary exposure assessments have been used in determining the need for food labelling (e.g. energy labelling on alcoholic beverages) and in consumer education materials (e.g. mercury in fish (FSANZ 2020b)).

There are some cases where dietary exposure assessments are unlikely to be useful. For example, the dietary exposure assessment techniques most commonly used by FSANZ are not useful or appropriate for assessing the risk associated with dietary exposure to an allergen where minute amounts in food may provoke a life-threatening reaction in only certain individuals.

2.4 FSANZ input into dietary exposure assessments at the global level

FSANZ developed a dietary exposure assessment capability in the mid-1990s in response to significant changes in food standards setting at the international level. FSANZ is recognised as being a world leader in the field of dietary exposure assessments, having made important

[5] Applications to FSANZ seeking to change the Australia New Zealand Food Standards Code are made by individuals, organisations or companies, whether from Australia, New Zealand or any other country. For information about making an Application to change the Code, applicants can refer to the FSANZ website www.foodstandards.gov.au. Information available on the website includes general information about the process of making an Application and what information needs to be submitted, including the types of information required.

[6] Proposals are prepared by FSANZ to consider changes to the Australia New Zealand Food Standards Code.

contributions to FAO, WHO and Codex developments in risk assessment and management, in particular providing input into the 1997 and 2005 FAO/WHO consultations on dietary exposure assessment, including development of guidelines for acute dietary exposure assessments (FAO/WHO 1997; WHO/FAO 2008). More recently, FSANZ has provided input into international guidance on conducting total diet studies (Moy and Vannoort 2013), and into the revision of *Chapter 6 of EHC (Environmental Health Criteria) 240* (FAO/WHO 2020a). FSANZ contributes significantly to the work of a number of Codex food regulation committees and associated technical committees. For example, FSANZ has been directly involved in the incorporation of dietary exposure assessments into the risk assessment process undertaken by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR)[7]. Further information on FSANZ's contribution to Codex is available on the FSANZ website (FSANZ 2023f).

JECFA establishes safe levels of exposure for food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs, and develops specifications for food additives (WHO 2023b). JECFA decisions are accepted internationally and are used by governments to assist in establishing national food standards (WHO 2023b). FSANZ provides regular input into JECFA safety assessments of food chemicals by attendance as dietary exposure experts and by submission of dietary exposure assessments for the Australian and New Zealand populations. The assessments submitted to JECFA use Australian and New Zealand food consumption data and Codex food chemical permissions, and/or chemical concentration data at the national level. JECFA provides scientific advice to the Codex Committees on food additives, contaminants and veterinary drug residues particularly in relation to the risk associated with particular levels of exposure to food chemicals of interest (WHO 2023b).

JMPR evaluates individual pesticides, reviews and establishes safe levels of exposure to pesticide residues (FAO 2024) and provides advice on the acceptable levels of pesticide residues in food moving in international trade (WHO 2024). Similar to those made at JECFA, the decisions made by JMPR are used internationally for risk assessment and are considered by the Codex Committee on Pesticide Residues (FAO 2024). FSANZ adopts Codex MRLs where appropriate through FSANZ MRL Harmonisation Proposals (see section 6.4). FSANZ provides input into JMPR assessments by attendance as dietary exposure experts.

Where appropriate, FSANZ also contributes directly to Codex meetings. Contributions from the dietary exposure assessment area may include information on the concentrations of chemicals in foods, food consumption data, the level of exposure to chemicals in foods, contributions of particular foods to total dietary exposure and assessments on the likely impact to Australian populations of changes in international food standards (e.g. maximum levels) for food chemicals. This information is useful in establishing the Australian position used in discussions at the Codex meetings and in setting international food regulations.

2.4.1 International best practice

FSANZ dietary exposure assessments are based on internationally established methodologies, such as those described in *Chapter 6 of EHC 240* (FAO/WHO 2009b; FAO/WHO 2020a). Developments at the international level are adopted and incorporated into FSANZ's dietary exposure assessments where appropriate.

[7] JECFA and JMPR are independent scientific expert committees which provide risk assessment advice to Codex, FAO and WHO (and their member countries).

2.5 Terms used by FSANZ

Different regulatory agencies may use different terms to describe the same thing. Below are terms and definitions frequently used by FSANZ throughout this document and in other publications, including webpages. Additional abbreviations, acronyms, terms used, and their definitions can be found in Appendix 2: Abbreviations and acronyms and Appendix 3: Glossary to this document and in the Glossary to the EHC 240 (FAO/WHO 2009a).

- **Exposure assessment** is a term that refers to the estimation of total exposure to a chemical from all sources including food, water, air and skin exposure. FSANZ mainly conducts dietary exposure assessments, focusing on exposure through food and drinking water. Other routes of exposure may be considered where appropriate and where the data are available; or may just be described qualitatively in the assessment reports produced. FSANZ generally uses the term **dietary exposure assessment** when referring to the assessments for all food chemicals apart from nutrients and those substances intended, at specific intakes, to produce a beneficial effect in the body. It may also be used to refer to dietary exposure assessments in general. In the case of nutrients or substances with a nutrition or health benefit, FSANZ uses the term **dietary intake assessment**.
- **Dietary modelling** refers to the mathematical techniques used to generate estimates of dietary exposure. Dietary modelling combines food consumption data with food chemical concentration data to estimate dietary exposure to food chemicals, or intake of nutrients (see Equation 1). This is usually summed for all foods containing the food chemical, and can be divided either by individual or mean (sub)population body weights (bw) where assessments are conducted for food chemicals for which the health-based guidance value[8] is expressed on a body weight basis (FAO/WHO 2020a) (see Equation 2 and section 4.3.1).

$$\textbf{Dietary exposure} = \sum (\text{food chemical concentration} \times \text{food consumption})$$

Equation 1: Dietary exposure assessment equation (FAO/WHO 2020a)

$$\textbf{Dietary exposure} = \frac{\sum (\text{food chemical concentration} \times \text{food consumption})}{\text{body weight (kg)}}$$

Equation 2: Dietary exposure assessment equation for comparison to a health-based guidance value expressed per kilogram of body weight (FAO/WHO 2020a)

- **Food chemical concentration** refers to the level or amount of a chemical in a set weight of food (e.g. 1 kg or 100 g). This may be at the raw commodity (e.g. milk), processed food (e.g. cheese), or 'as eaten' (e.g. pizza) food level.
- **Food consumption** refers to the amount of food and beverages consumed or eaten by populations or population sub-groups.
- ***Harvest*** is FSANZ's custom built computer application that is used to calculate dietary exposure to food chemicals (see section 5.13). Detailed information about *Harvest* is available on the FSANZ website (FSANZ 2023i).

[8] Previously referred to as reference health standards.

- In risk assessment, dietary exposure estimates are compared with **health-based guidance values** (HBGVs) where available, to assess the potential risk to health associated with changes to the food supply (see section 4.6). These HBGVs relate to the accepted level of exposure below which adverse health effects are considered not to occur. In the case of nutrients, they may relate to the intake level the population should be reaching to achieve optimal health, a level of nutrient adequacy, or a maximum level or upper level of intake. Where a population's dietary intake is above the HBGV for nutrient adequacy or below the upper limit, the likelihood of an adverse health effect is negligible.
- Dietary exposure estimates may be for **long term** or **short term** exposures. The choice of dietary exposure estimate type depends on the nature of the hazard posed by the chemical (**chronic, shorter-than-lifetime** or **acute**) and the HBGV established. Different concentration and food consumption data sets are required for each of these assessments (see section 5.4).
- Dietary exposure results may be presented for **all respondents** in the population (eaters and non-eaters of foods containing the chemical of interest) or **consumers only** (eaters of foods containing the chemical of interest or of foods proposed to contain the chemical of interest). For some food chemicals e.g. some contaminants and nutrients, the dietary exposure results will be practically the same for 'all respondents' and 'consumers'. This is because these food chemicals are in nearly all foods in the food supply, and all survey respondents will consume at least some of these foods and be counted as a 'consumer'. For intentionally added food chemicals, e.g. food additives, pesticides, and veterinary drugs, nutrients in dietary supplements or naturally occurring toxicants occurring in specific foods, there can be a big difference between the dietary exposures for 'all respondents' and 'consumers only'. In assessing risk for these chemicals, FSANZ reports exposures for 'consumers only' because they are the people who are likely to be exposed to the food chemical of interest.
- By their very nature, dietary exposure assessments can only **estimate** (or model) the real situation with regard to dietary exposure to food chemicals. The reliability, accuracy and value of estimated food chemical dietary exposures are founded on the quality of the original data inputs (such as the food chemical concentration data and food consumption data) and the assumptions made through the assessment process.

3 FSANZ DIETARY EXPOSURE ASSESSMENT PRINCIPLES

FSANZ has developed a number of principles that underpin its dietary exposure assessments.

- Dietary exposure assessments are an integral part of risk assessments as the level of risk to public health and safety resulting from chemical hazards and nutrients in food is dependent on the level of exposure.
- The objective of the dietary exposure assessment should be clearly defined.
- It is desirable to make the best estimate of dietary exposure for the assessment task at hand, using the best available data and world's best practice methodology. However, the selected dietary exposure assessment techniques should be no more complex than is necessary to answer the regulatory, risk assessment or risk management question(s).
- The most robust HBGVs established using the available data should be used in dietary exposure assessments. Wherever possible, HBGVs set by international food regulatory agencies or other reputable bodies, such as those set by JECFA, JMPR, the National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health will be considered in the first instance. If established HBGV are current, robust and suitable they will be used for dietary exposure assessment purposes in preference to *de novo* establishment of values by FSANZ. Where necessary, due to additional available data or identified limitations with established HBGVs, FSANZ will independently establish a HBGV or if practicable, work with those other bodies to jointly revise existing values to guide its risk assessment.
- Dietary exposure assessments should cover the general population as well as vulnerable population sub-group(s) that are identified in the hazard characterisation or based on the food types that contain the hazard.
- Dietary exposure assessments should take account of the duration of exposure required for the realisation of the toxicological endpoint, as considered in the hazard characterisation (e.g. acute/short term or chronic/long term hazard). This may also affect the population groups included in the exposure assessment.
- Dietary exposure assessments should consider that some population sub-groups have higher levels of exposure to food chemicals than the general population (or for nutrients, relatively lower levels) and the level of exposure for these groups.
- Uncertainties relevant to the dietary exposure assessment will be reported. Where there are significant uncertainties in the input data, assumptions that are applied will aim to be conservative. That is, they will aim to ensure that dietary exposure is not underestimated (toxicological safety) or overestimated (nutrient inadequacy).
- The methodology used, data sources and assumptions made, such as the level of conservatism and uncertainty in the dietary exposure assessment, should be effectively documented and communicated in the assessment report. This will facilitate understanding of the dietary exposure assessment outcomes for risk characterisation, risk management and risk communication purposes.

There are many different considerations that need to be made before starting a dietary exposure assessment. Figure 3 sets out the general steps that FSANZ follows in conducting a dietary exposure assessment with the corresponding section of this document in brackets. The data sources and methods used in dietary exposure assessment at FSANZ are described in Chapters 4 and 5.

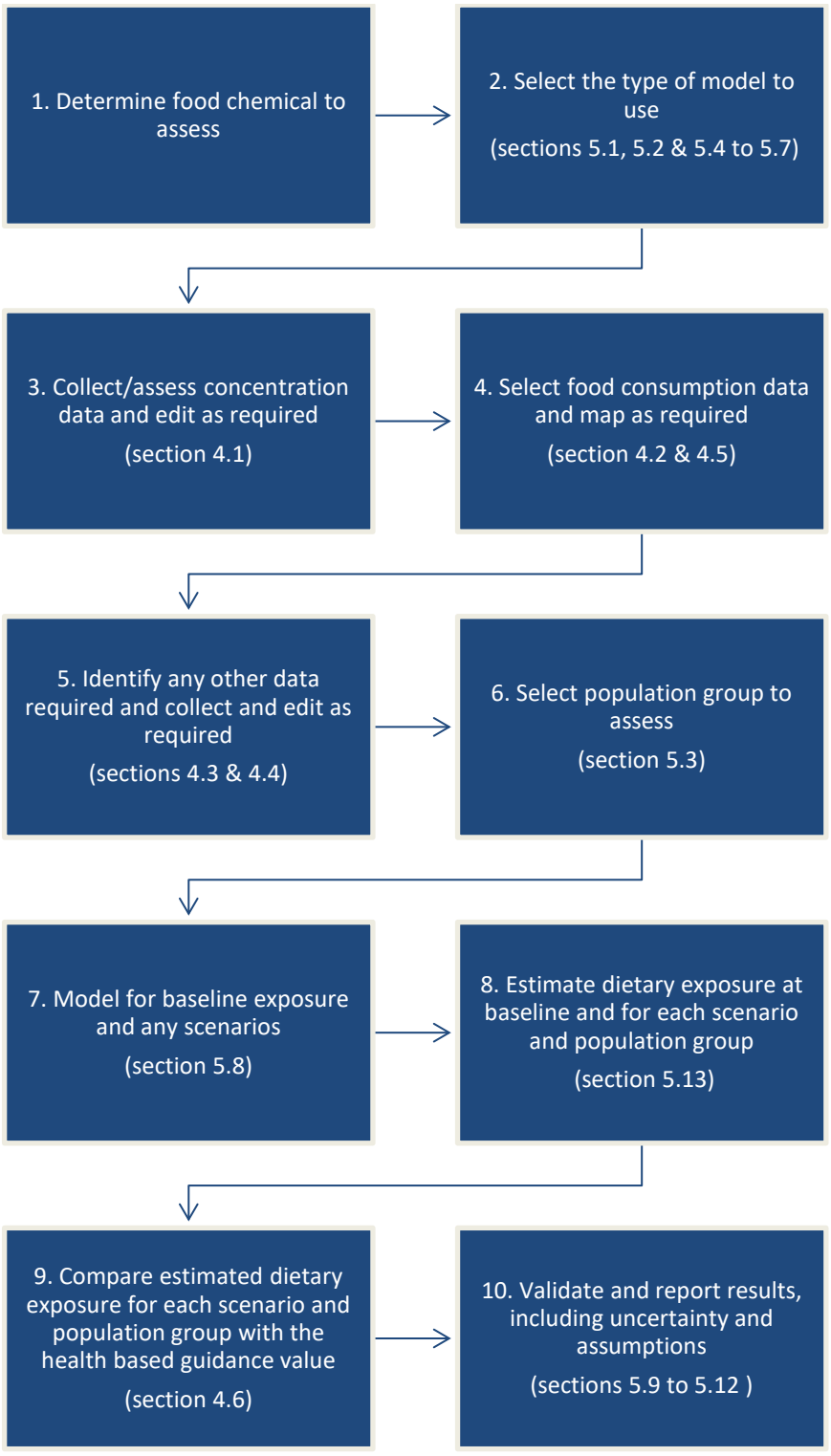

Figure 3: The general steps in undertaking a dietary exposure assessment at FSANZ

4 DATA SOURCES FOR DIETARY EXPOSURE ASSESSMENT

Two key data sources are required to conduct dietary exposure assessments – food chemical concentration data and food consumption data (sections 4.1 and 4.2 respectively, Figure 3). Food consumption data need to be compiled and managed in ways that are relevant to the exposure assessments being undertaken. These and other relevant issues are discussed in sections 4.3 to 4.6.

4.1 Food chemical concentration data

FSANZ considers many factors when collecting or collating food chemical concentration data for dietary exposure assessment purposes. These factors include:

- the purpose of the assessment
- what foods are of interest
- the availability and extent of concentration data
- data quality and format.

At the start of each dietary exposure assessment, the data available are evaluated. Where data gaps exist, FSANZ may try to obtain the relevant data required for the assessment or may ask Applicants to provide data.

4.1.1 Sources of food chemical concentration data

There are many different sources of food chemical concentration data, with major sources summarised in Table1 below.

Table 1: Summary of sources of food chemical concentration data

Food chemical type	Sources of concentration data
Contaminants and natural toxicants	• maximum levels (ML) from food standards • proposed ML • analytical survey data including monitoring and surveillance data • scientific literature including international databases
Agvet chemical residues	• MRL from food standards • proposed MRL • analytical survey data including monitoring and surveillance data • supervised trial residue data
Food additives, Novel foods, Processing aids	• maximum permitted levels (MPL) from food standards • manufacturer use levels • analytical survey data • proposed use levels • food labels
Nutrients, Nutritive substances	• food composition databases • analytical survey data including monitoring and surveillance data • proposed or actual use levels (fortification) • maximum permitted amounts or claimable levels[9] from food standards • food labels and branded food databases
Packaging materials	• chemical migration data • analytical survey data including monitoring and surveillance data
Flavouring agents	• manufacturer use levels

FSANZ prefers to use chemical concentration data from Australia and New Zealand for dietary exposure assessments, however sometimes such data are not available. In this case, data from other countries may be used, after assessment of their relevance to the Australian and New Zealand situations. For example:

- If a food is mostly imported into Australia or New Zealand, it may be appropriate to use overseas data for dietary exposure assessments.
- Food chemicals that occur as a result of food processing may be present at similar levels in foods from different countries and therefore it may be appropriate to use overseas data for these chemicals.
- Food additive or processing aid residues may be present at similar levels in foods from different countries as there are technological levels of use and therefore it may be appropriate to use overseas data for these chemicals.
- For contaminants and natural toxicants that vary from country to country due to environmental differences, data from other countries may not be appropriate.
- Nutrient data from other countries may also not be appropriate due to differing fortification practices and food production conditions.

4.1.1.1 Levels/limits in food standards

In the absence of information on actual levels of chemicals in foods, FSANZ may use maximum levels/limits (e.g. ML, MPL, MRL) established in the Code or in international

[9] Claimable levels refer to the maximum amount of a nutrient that can be claimed as a percent of a reference quantity. These are prescribed within the Australia New Zealand Food Standards Code for different foods and the vitamins and minerals in them. These levels ensure that Nutrient Reference Values (NRVs) such as Recommended Dietary Intake (RDI) are not exceeded, while providing manufactures compositional flexibility when formulating products.

regulations (e.g. *Codex General Standard for Food Additives* (FAO/WHO 2023c)), or proposed in an Application or Proposal for the purposes of dietary exposure assessment. Because in practice maximum levels are generally above actual levels, use of maximum levels is likely to substantially overestimate dietary exposure to food chemicals. However, if maximum levels are used, this will provide an indication as to whether or not exposure under a 'worst case' scenario could approach a HBGV. If dietary exposure is estimated to be below the relevant HBGV, there is unlikely to be a need to obtain more realistic concentration data to undertake a more refined assessment (FAO/WHO 2020a). However, if the worst-case exposure approaches or exceeds the HBGV, more realistic chemical levels (e.g. from analytical surveys or manufacturer use data for example) can be used to provide a more realistic estimate of exposure.

For dietary exposure assessments of microorganisms added to food, FSANZ may use minimum levels established in the Code or in international regulations, or proposed levels of use/addition, e.g. for microorganisms used in the manufacture of fermented foods such as milk or yoghurt.

4.1.1.2 Manufacturer use levels

In many cases, particularly those relating to the assessment of food additives, processing aids, or novel foods, the only food chemical concentration data available to FSANZ for use in dietary exposure assessments will be data provided by the Applicant or the food industry on the proposed, likely or actual levels of use of the chemical in question. These data would be used in the dietary exposure assessment on the assumption that the amount added to a food is equal to the amount remaining in the food as consumed, which may be an overestimation (FAO/WHO 2020a), e.g. where the chemical is destroyed, reduced or removed during the production process, or where it degrades during storage. The mean, median, high concentration and/or maximum proposed or actual level added for a given food or food group may be selected depending on the purpose and nature of the dietary exposure assessment (see section 4.1.4).

4.1.1.3 Food composition databases

Food composition databases contain analytical, calculated, borrowed and imputed data on the nutrient composition for a wide range of foods available in the country (FAO/WHO 2020a). In Australia, FSANZ compiles and maintains the reference Australian Food Composition Database (FSANZ 2023c), in addition to AUSNUT 2011-13 (FSANZ 2023b) which is a set of files used to estimate food, dietary supplement, and nutrient intakes from the 2011-13 Australian Health Survey (AHS). In New Zealand, the Ministry of Health and the New Zealand Institute for Plant and Food Research Limited (2022) compile the New Zealand Food Composition Database. Both the Australian and New Zealand food composition database websites have search functions for specific foods and nutrients in addition to downloadable data files.

4.1.1.4 Branded food databases

FSANZ is currently developing the Australian Branded Food Database, collating on- and off-pack label data from industry that may be used in dietary exposure assessments. Data that are anticipated to become available on the FSANZ website include nutrition information panel data and ingredient statements. For further information, refer to the FSANZ website (FSANZ 2022).

In New Zealand, the On Pack label database is used by the Ministry for Primary Industries (MPI) to monitor changes to the New Zealand food supply. These data may be used by

FSANZ for its risk assessment purposes, or in joint risk assessments with MPI. For further information refer to the GS1 New Zealand website (GS1 New Zealand 2023).

This information may be useful to determine the types of foods and/or the proportion of foods of a certain type containing certain food additives or fortificants.

4.1.1.5 Analytical survey data

The FSANZ dietary exposure assessment team has good linkages with the FSANZ food composition and surveillance areas. The teams collaborate in collecting and compiling analytical survey data used for dietary exposure assessments, including from the ATDS (section 4.1.1.5.1). FSANZ will also collect analytical survey data from other groups including Australian (including State and Territory), and New Zealand government agencies, the food industry, universities, or from published scientific literature as required. Issues associated with analytical survey data quality are discussed in sections 4.1.1.5.2 to 4.1.1.5.4.

4.1.1.5.1 Total diet study (TDS) data

Total diet studies (TDSs) are one class of analytical survey for which FSANZ generally performs a dietary exposure assessment and also uses the reported chemical concentrations for subsequent risk assessments. TDS are conducted in both New Zealand and Australia by MPI (Ministry for Primary Industries 2023b) and FSANZ respectively. Australian and New Zealand TDS results are presented in a formal report and the analytical data are available for use in other dietary exposure assessments and may be combined with other data sets.

The purpose of a TDS is to estimate the level of chronic/long term dietary exposure of the population to a range of chemicals that may be found in the food supply (FAO/WHO 2020a). Traditionally, the Australian studies have focussed on dietary exposure to a range of agvet chemical residues and contaminants. However over time, the focus of these studies has expanded to consider a broader range of food chemicals, including food additives, nutrients, environmental contaminants and natural toxicants. The New Zealand studies have covered a similar range of chemicals and nutrients (Ministry for Primary Industries 2023b).

The reliability of TDS data depends on the careful selection of sampled foods and preparation methods, and inclusion of sufficient foods, so that the results are representative of the diversity of the food supply (FAO/WHO 2020a). In Australia and New Zealand, around 100 different foods are typically selected, and these are foods that are widely consumed as well as those foods known to have high levels of the chemicals being assessed. Multiple samples of each food are collected from across each country, at more than one time in a year to capture seasonal variation. There is generally compositing of samples in which case individual analytical results are averages of multiple sub-samples (FSANZ 2023d; Ministry for Primary Industries 2023b). Foods are prepared as normally consumed (e.g. boiled pasta, fried meat, brewed tea etc.) in a TDS as opposed to raw commodities (FAO/WHO 2020a).

The advantages of the total diet approach include:

- robust data are generated on levels of a food chemical across the food supply
- the data generated reflect chemical concentrations in food as consumed by using commonly used food preparation and cooking procedures
- if repeated, studies can be used to assess trends in food chemical concentrations and dietary exposure to these chemicals

- they provide a mechanism to determine which food groups are the major dietary sources of the food chemical; this can help to identify the food groups where more concentration data could be collected
- the studies provide 'background' data in the event of local contamination.

A limitation of TDSs is that, by compositing individual samples, information on variability in levels of food chemicals is reduced. This is particularly relevant when assessing dietary exposure to food chemicals that are not uniformly distributed across foods or are present in foods that may be consumed in large amounts by some population sub-groups.

Further information on TDS methodology can be found in *Chapter 6 of EHC 240* (FAO/WHO 2020a). Information on specific Australian or New Zealand TDSs are available online (FSANZ 2023d; Ministry for Primary Industries 2023b).

4.1.1.5.2 Analytical survey data quality

FSANZ has no set minimum data requirements for analytical survey data. All analytical survey data are assessed on a case by case basis in order to determine whether they are of adequate quality and quantity, and appropriate for the dietary exposure assessment being conducted. That is, the data provided must meet the needs of the assessment and not result in an unrealistic estimate of dietary exposure.

The characteristics of the data that are assessed include but are not limited to, those described in Table 2.

FSANZ documents the source of, and limitations associated with, the concentration data used for dietary exposure assessments. Should the data for a particular assessment be inadequate, FSANZ may initiate, or suggest the need for a program to collect more data.

Table 2: Assessment of analytical survey data quality

Data characteristic	Assessment questions
Age and currency	• Were the data collected before a major change to the food supply that would affect the values obtained? • Do the products surveyed reflect those now on the market in Australia and/or New Zealand?
Survey design	• Were the data from a broad ranging survey or from a targeted survey, for example, of likely non-compliant products or conducted in contaminated areas? • Were the sample selection and collection methods representative and appropriate (e.g. consideration of factors such as geographical region, season, variety, brand, cooking method)?
Analysis method	• Is the Laboratory accredited? • Is the method of analysis accredited? • Was the method of analysis appropriate (e.g. a standard or validated method)? • Is there an improved method of analysis now available? • Did the survey measure the chemical of interest within the required limit of detection?
Number and range of data points	• Are there sufficient data to ensure a representative dataset and enable robust conclusions to be reached? • Do the data need to be extrapolated to cover related foods (e.g. to juice from fresh fruit)?
Relevance to the assessment being undertaken	• Do the data cover the types of foods being assessed (e.g. raw vs cooked, domestic vs imported, fresh vs processed)?

4.1.1.5.3 Analytical survey design

Analytical surveys are resource intensive but can provide important data to inform dietary exposure estimates. In practice it is common that food chemical concentration data available for dietary exposure assessments are imperfect and not fully representative of the chemical and foods being studied. For example, samples may have been selected from a limited region or over a limited time frame, or insufficient samples may have been collected to allow for the wide variation in food chemical levels that may occur. Where samples are composited prior to analysis, information on variation in chemical concentration can be reduced as the analysed values will essentially be average values (FAO/WHO 2020a). This reduces the flexibility of the data for dietary exposure assessments based on probabilistic modelling techniques (section 5.2.3), for scenario modelling (section 5.8), and for acute/short term dietary exposure assessments (section 5.4.1).

Compliance survey data are generally not used in dietary exposure assessments at FSANZ because they are usually based on non-representative sampling plans or may use simplified analytical techniques that only assess whether or not a food meets a regulatory limit, rather than quantifying the level of the chemical in question (FAO/WHO 2020a). However this type of survey data may still be useful, for example in assessing the proportion of foods that may

be contaminated, or the range of potential contaminant levels that could be found in a more broad-based survey.

As noted above for national assessments FSANZ avoids data collected in a targeted manner, such as where there was a localised chemical spill. Concentrations from targeted sampling are very unlikely to be relevant to the whole population. However, FSANZ may determine that a separate exposure assessment for a particular population sub-group is warranted should the data indicate a difference in concentration levels in food eaten by that group compared to the same food that is consumed by the majority of the general population.

4.1.1.5.4 Treatment of 'non detected' and 'trace' results

Within analytical data sets there may be concentrations of a food chemical that are shown as 'non-detected' or below the limit of detection (LOD), limit of quantification (LOQ) or limit of reporting (LOR)[10] for the analytical method (FAO/WHO 2020a). There may also be concentrations reported as 'trace' which are between the LOD and the LOQ (i.e. the concentration has been detected but cannot be quantitated). For the purposes of a dietary exposure assessment, FSANZ needs to assign these concentrations a numerical value to allow calculation of a representative value for use in dietary exposure estimates. There are a number of values that FSANZ may assign, depending on the type of chemical being assessed.

For concentrations reported as 'non-detected' FSANZ may assign:

- value equal to zero (generally referred to as a 'lower bound' value)
- value equal to half the LOD or LOQ ('middle bound')
- value equal to the LOD or LOQ ('upper bound')
- a range of values between zero and the LOD or LOQ (FAO/WHO 2020a).

For concentrations reported as 'trace' FSANZ may assign:

- value equal to the LOD ('lower bound')
- value equal to the mid-point between the LOD and LOQ ('middle-bound')
- value equal to the LOQ ('upper bound').

The treatment of non-detected and trace results is considered on a case by case basis. Factors include:

- the type of food chemical being assessed
- whether the food chemical is deliberately added to foods or naturally occurring
- whether essentiality and safety are being assessed e.g. for nutrients
- the number or proportion of not detected results in the dataset
- the magnitude of the LOD/LOQ in relation to the HBGV (FAO/WHO 2020a)
- the parameters of the analytical method e.g. if the method had a higher LOD than levels provided from previous analyses or other sources

[10] The limit of reporting (LOR) can be based on the LOD, LOQ or another value e.g. a value >LOQ.

- the purpose of the assessment.

FSANZ will report the approach it has used in dietary exposure assessments to deal with non-detected and trace results and will attempt to identify the effect of this on likely exposure estimates. Where the food chemical is likely to be present in the food (e.g. naturally occurring contaminants and toxicants) FSANZ will typically report exposures for both lower and upper bound concentrations (FAO/WHO 2020a). Further details about which of the options above are used for specific types of food chemicals is outlined below in the sections relevant to those chemicals.

4.1.2 Mode of expression of food chemical concentration data

Some manipulation of food chemical concentration data may be required before their use in dietary exposure assessments.

Firstly, the concentration data need to refer to the same form of the food that is cited in the food consumption data, such as raw or cooked, dried or prepared. For example, a concentration value for a chemical in coffee powder needs to be converted to a concentration that would be in fluid coffee before using it to calculate dietary exposure from coffee as consumed.

Additionally, the concentration data need to be expressed in the same chemical form as the HBGV. For example, nitrites are a food additive permitted for use in the Code as potassium or sodium nitrite, however, the HBGV is expressed as the nitrite ion. Therefore, a conversion based on molecular mass would be used to convert the added form in food to an equivalent concentration of the relevant ion for dietary exposure assessment and risk characterisation purposes.

Some food chemicals are assessed as a group, for which levels of the individual chemicals or congeners are summed for the assessment. This may or may not take into account the relative potencies of the individual chemicals. An example is dioxins, where hundreds of individual chemicals exist in this group. They share a common mode of toxicity, of which 29 individual congeners have been identified as having significant toxicity (WHO 2016). Each of the 29 individual chemicals has a toxic equivalency factor (TEF) which ranks its toxicity in relation to the most potent chemical. The WHO TEF values were most recently updated in 2022 (DeVito et al. 2024). In order to conduct a dietary exposure assessment, the concentration for each individual chemical must be multiplied by its TEF before summing the concentrations to obtain a single concentration for the chemical as a group in the food analysed.

4.1.3 Combining data from different sources

FSANZ will often collect concentration data for a food chemical in a given food or food category from a number of different sources that may have been collected and analysed in different ways. FSANZ assesses each data set on its merits before determining whether any can be combined to create a larger data set that is more representative of the levels likely to be found in the food supply. In combining data sets FSANZ will examine factors such as:

- the analytical methods used
- the purpose and size of each data set
- whether results from individual or composite samples are reported
- whether or not different data sets should be weighted prior to combining
- whether the same type and form of food had been analysed

- the analytical quality of each data set.

Additional refinements to the process for pooling data have to be considered in cases where raw data are derived from different surveys with different reported LODs/LOQs (FAO/WHO 2020a). There are several options for doing this, and the option selected will be carefully chosen to minimise sample bias and give the best possible combined data set for the purposes of the dietary exposure assessment.

4.1.4 Selecting concentration data to use for dietary exposure assessments

It is possible to conduct dietary exposure assessments using several measures of a food chemical concentration in the foods of interest depending on the purpose of the assessment. For example, the dietary exposure assessment may be conducted using a mean, median or high concentration value derived from a data set.

In the semi-probabilistic approach to dietary exposure assessment that FSANZ usually uses (see section 5.2.2 for further information on this approach), a single food chemical concentration value is selected for each type of food or food group included in each model. Therefore decisions need to be made on how to derive this single value in situations where a number of values are available to use.

4.1.4.1 Selecting a concentration to use for chronic dietary exposure assessments

Median, mean and mode are statistical measures of central tendency that may be used to represent concentration levels in chronic/long term dietary exposure estimates. In normal distributions of data, the mean (arithmetic average), mode (value with the highest frequency) and median (50^{th} percentile) will be very similar. However, in skewed distributions of data these measures may give different values. Where the distribution of levels of food chemicals or nutrients is positively (or right) skewed (mostly lower values with a smaller number of higher values), as is typically found in surveys of food contaminants and natural toxicants (see Figure 4), the median concentration level rather than the mean concentration level may be used in a dietary exposure assessment in order to avoid overestimating exposure (FAO/WHO 2020a). Other considerations for specific food chemicals are provided below. Further options are also discussed in *Chapter 6 of EHC 240* (FAO/WHO 2020a).

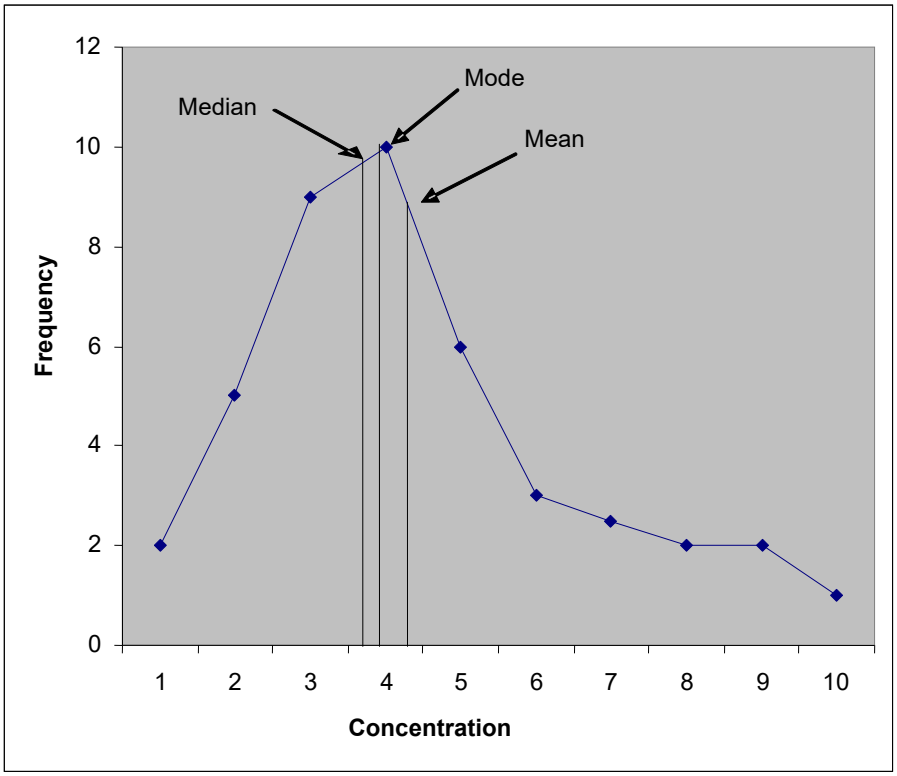

Figure 4: Measures of central tendency in a positively skewed distribution

For **contaminants and natural toxicants**, FSANZ usually uses the mean concentration, however the median may also be selected for example, where the data are positively skewed (see above). Where there are a large number of results less than the LOD/LOQ and where the contaminant or natural toxicant is reasonably expected to be present in the food, FSANZ may use the mean in a conservative approach so exposure is not underestimated. A mean may also be used where analytical data from composite samples are available as averaging of the concentration has already occurred during the sample compositing process (FAO/WHO 2020a). This is usually the case for results from total diet studies.

In choosing **agvet chemical residue** concentration levels from supervised trials for use in chronic/long term dietary exposure assessments, FSANZ has traditionally followed the Codex convention in using the median concentration rather than the arithmetic mean, reflecting the likelihood of skewed concentration distributions for these chemicals (FAO/WHO 2020a). For similar reasons as discussed for contaminants and natural toxicants (see above) FSANZ may also use the mean concentration when data are from an analytical survey.

For chemicals that are intentionally added to foods (e.g**. food additives, novel foods** and **nutrients**), mean concentration values are used in chronic/long term dietary exposure assessments as they are considered to be representative of concentrations that a person would consume over a lifetime (FAO/WHO 2020a). The selected nutrient concentrations would also take naturally occurring levels into account, usually presented as mean concentrations in food composition datasets. If conducting a consumer behaviour assessment (see section 5.7), a concentration higher than the mean may be selected.

4.1.4.2 Selecting a concentration to use for acute dietary exposure assessments

In acute/short term dietary exposure assessments, a high concentration value is usually selected, for example, the highest residue reported for a pesticide in a food in an agricultural trial (FAO/WHO 2020a) (see sections 5.4.1, 6.4.2.1). If a distribution of concentration data are available, the highest reliable concentration (depending on the number of data points) can be selected (FAO/WHO 2020a). Summary concentration data (e.g. mean, median) are not suitable for acute dietary exposure assessments (FAO/WHO 2020a).

4.1.5 Variability and uncertainty in food chemical concentration data

"Variability and uncertainty are inherent in the risk assessment process" (FSANZ 2013a p. 55). Variability relates to differences with a parameter (e.g. differences in pesticide residue concentrations between different samples taken from the same food batch) and cannot be reduced. Uncertainty relates to a lack of knowledge within a parameter and can be reduced through the use of additional or more accurate data (FSANZ 2013a).

Levels of chemicals in foods can be highly variable, even within the same type of food. Many factors affect this variation including season, location of sample, soil types, agricultural practices, batch-to-batch variation in processed foods, variety and many others. When levels of a food chemical are highly variable, it is preferable to draw on a large primary sample to generate a more robust estimate of the distribution in concentration of the chemical. Although more and better information will not change the variability in any way, it helps us to better understand it.

Variation in food chemical concentration influences overall uncertainty in the concentration that is assigned to a food for exposure assessment purposes, but is not synonymous with uncertainty. Many other factors influence the overall uncertainty associated with a value, including sampling uncertainty, measurement uncertainty and uncertainty in assigning these concentration data to the foods reported as consumed in nutrition surveys. These other factors can be controlled to some extent by processes used to determine food chemical concentration, for example by use of improved methods of analysis.

Sampling uncertainty or error can arise for a number of reasons, such as when insufficient samples have been selected, the wrong samples have been purchased, the samples are not representative or samples have not been prepared or stored correctly (e.g. the sample may have become contaminated or have deteriorated). It is not always possible to identify these problems although cross-checking with sample photos can assist. If maximum limits from regulation are used in a dietary exposure assessment, sampling uncertainty does not apply, but the exposure estimates are likely to be far higher than actual exposure (FAO/WHO 2020a).

In a FSANZ dietary exposure assessment, a single food chemical concentration is generally used for a particular food. In reality, this single value has an unstated uncertainty associated with it. Another source of uncertainty is the assignment of concentration data measured in one food to individual foods reported as consumed in nutrition surveys. It is difficult to quantify the magnitude of this uncertainty but it is reduced by mapping of analysed foods to nutrition survey foods, the use of appropriate recipes, (see sections 4.5.3 and 4.5.4), and through staff experience and judgement.

FSANZ will identify such areas of uncertainty in dietary exposure assessment reports. In some assessment reports, FSANZ may provide qualitative or quantitative information on the uncertainty associated with some or all concentrations used and in some cases may produce a range of potential dietary exposure estimates. For further information about

variability and uncertainty in food chemical concentration data, including the types of errors contributing to uncertainty please refer to *Chapter 6 of EHC 240* (FAO/WHO 2020a).

4.2 Food consumption data

Food consumption data are the other major data source required along with chemical concentration data to conduct dietary exposure assessments. The type of food chemical and the purpose of the assessment determines:

- the most appropriate source of data for the assessment
- how any existing source of consumption data (e.g. national nutrition survey data) needs to be used for the assessment.

There are many methods that can be used to collect food consumption data. Food consumption data can either be collected from individuals or obtained at an aggregate level (such as national data), then converted to per-person values.

4.2.1 Methods for collecting food consumption data from individuals

4.2.1.1 24-hour recall

The most commonly used method of collecting nationally representative, quantitative information on food consumption is the 24-hour recall. This is the method used in national nutrition surveys (NNSs) in Australia and New Zealand, and in many other countries. In a 24-hour recall, each individual is interviewed and the foods eaten and amounts consumed are recorded for the previous 24-hour period. The 24-hour recall method relies on people being able to remember what they consumed and estimate the amounts consumed with reasonable accuracy. Good survey design such as the use of multi-pass methods and portion size images assists with this (FAO/WHO 2020a). In some surveys a second, non-consecutive 24-hour recall may also be conducted for some or all respondents. As an individual's food consumption can vary greatly day to day, food consumption estimates based on a single 24-hour recall do not reflect long term consumption. Data from a second non-consecutive 24-hour recall day can be used to adjust for this day-to-day variation (FAO/WHO 2020a), improving the accuracy of longer-term food consumption estimates and therefore chronic dietary exposure assessment estimates. Other adjustments can be made when only one day of food consumption data are available (see section 5.5).

4.2.1.2 Food record

A food record or food diary is a food consumption data collection method that requires individuals to weigh or estimate the amount of all the foods they consume across the day and record this, along with details about the types of foods (FAO/WHO 2020a). Food records are usually completed for one, three, seven or 14 days. Image-based food records (i.e. images recorded using a mobile device application) are increasingly being used to provide additional data on quantities and types of foods consumed (Tanweer et al. 2022). Food records may be more accurate than 24-hour recalls in recording all foods consumed and their amounts, however respondents may change their eating habits to make it easier to weigh foods and there is a higher respondent burden for this type of collection method (Bailey 2021). Food records are sometimes used in surveys that FSANZ may draw on in conducting dietary exposure assessments, generally when there is need for more detailed information on consumption of a particular food or smaller group of foods than can be provided from 24-hour recall data.

4.2.1.3 Food frequency questionnaires

Food frequency questionnaires (FFQ) are another method of collecting food consumption data from individuals and record how often an individual eats certain foods, usually during the previous 12 months. Some FFQs also collect semi-quantitative estimates of consumption amounts by listing one or more portion sizes that the respondent refers to when estimating their frequency of consumption (FAO/WHO 2020a). The list of foods in an FFQ can range from a few foods up to around 200 (Dao et al. 2019) and therefore may not cover the full diversity of foods consumed by a population. Generally, FFQs do not provide adequate data for FSANZ's dietary exposure assessment purposes because not all consumed foods are captured and there is insufficient detail on specific foods eaten and amounts consumed. Despite these limitations, food consumption data from FFQs may be used to help interpret findings based on 24-hour recalls or food records, and to assist in risk characterisation, particularly for occasionally consumed foods[11]. For example they may help to identify those foods that are eaten by most people on a daily basis, such as bread and milk, and those people who never consume a particular food. The latter information is particularly useful in developing a more accurate estimate of long term risk for consumers of a food.

4.2.1.4 Food behaviour questions

Questions related to food consumption behaviours are often included when collecting data from individuals using the methods described above (FAO/WHO 2020a). These questions collect data on food habits such as addition of fat during cooking, types of fats and oils used (e.g. saturated, polyunsaturated or monounsaturated), trimming of fat from meat, consumption of full fat or reduced fat dairy products, and addition of salt during cooking or at the table. Again, these data are used to help put into context the estimated dietary exposures based on 24-hour recall or food record data or to assist in making assumptions for a given assessment.

4.2.2 Food consumption surveys for individuals

The highest quality food consumption data for conducting dietary exposure estimates are data collected from individuals through surveys that are representative of the population group being assessed. The most recent NNS data that FSANZ uses for dietary exposure assessments are outlined further below. Table 3 summarises some key features of each of the NNSs used regularly by FSANZ. The information does not include all surveys that may exist, but only those currently used by FSANZ for risk assessment purposes.

[11] Foods that are consumed less than once a week by 75% of the population or more are considered to be 'occasionally' consumed (FSANZ 1999).

Table 3: Features of national nutrition surveys used in FSANZ dietary exposure assessments

Feature	2011-12 NNPAS	2012-13 NATSINPAS	2002 NZCNS	2008/09 NZANS
Age group	2 years and above	2 years and above	5 - 14 years	15 years and above
Number of respondents Day 1 (day 2)	12,153 (7735)	4,109 (771)	3,275 (505)	4,721 (1180)
Duration	13 months May 2011 to June 2012	11 months August 2012 to July 2013	10 months February to December 2002	12 months October 2008 to October 2009
Sampling method	Household-based sampling with oversampling of selected groups	Household-based sampling with oversampling of selected groups	School-based sampling with oversampling of selected groups	Household-based sampling with oversampling of selected groups
Primary food consumption data collection method	Two non-consecutive 24-hour recalls 64% of respondents completed a second 24-hour recall	One 24-hour recall in remote areas Two non-consecutive 24-hour recalls in non-remote areas (43% completion rate)	Two non-consecutive 24-hour recalls 15% of respondents completed a second 24-hour recall	Two non-consecutive 24-hour recalls 25% of respondents completed a second 24-hour recall
Other food consumption data collected	Short questions on food Quantified dietary supplement use	Short questions on food Quantified dietary supplement use	Short questions on food Quantified dietary supplement use Food frequency questionnaire	Short questions on food Quantified dietary supplement use
Method of adjusting for long term nutrient intake	NCI method (see section 5.5.2.2.3)	N/A	Within-person variance adjustment method (see section 5.5.2.2.1)	Within-person variance adjustment method (see section 5.5.2.2.1)
Method of adjusting for long term food consumption or exposure (other than nutrients)	Each individual's exposure or consumption is averaged over two days	N/A	Not generally possible	Not generally possible
Population sampling weights used in *Harvest* (see section 4.3.2)	Day one and day two	Day one only	Day one only	Day one only
Reference	ABS (2013a)	ABS (2013b)	Ministry of Health (2003)	University of Otago and Ministry of Health (2011)

4.2.2.1 Australian National Nutrition Surveys

The most recent NNS for the general population in Australia that is available for use is the 2011-12 National Nutrition and Physical Activity Survey (2011-12 NNPAS). The 2011-12 NNPAS was a major component of the overarching 2011-13 AHS conducted by the Australian Bureau of Statistics (ABS) (ABS 2012). The 2011-12 NNPAS collected the following types of dietary data:

- 24-hour recall of food, beverages and dietary supplements
- food behaviour questions including:
    - usual dietary behaviours
    - avoidance of foods due to allergy/intolerance or cultural, religious or ethical reasons
    - whether currently on a diet to lose weight and/or for health reasons; and if so, the type of diet (ABS 2013a).

A total of 12,153 persons aged 2 years and above completed one 24-hour recall, with 64% of respondents also completing a second 24-hour recall on a non-consecutive day (ABS 2013a).

FSANZ uses the 2011-12 NNPAS data for most dietary exposure assessments for Australians. Individual confidentialised records are mostly used for this purpose, however aggregated population statistics as reported in the summary publications noted above may also be used.

Several publications were produced from the 2011-12 NNPAS and are available on the ABS website. These include:

- Nutrition First Results - Food and Nutrients (ABS 2014b)
- Nutrition-Supplements (ABS 2015b)
- Usual Nutrient Intakes (ABS and FSANZ 2015)
- Consumption of Food Groups from the Australian Dietary Guidelines, 2011-12 (ABS 2016b)
- Consumption of Added Sugars (ABS 2016a).

FSANZ previously used data from Australian NNSs conducted in 1983, 1985, 1995, and 2007. Data from these surveys are no longer used by FSANZ for risk assessment purposes as the 2011-12 NNPAS provides the most up-to-date source of individual food consumption data for the general population in Australia aged 2 years and above. These older datasets however may be used to analyse trends in dietary intake or exposure over time, such as for vitamin A (Messina et al. 2019).

Between August 2012 and July 2013, the ABS conducted the first NNS of Aboriginal and Torres Strait Islander peoples aged 2 years and above as part of the 2011-13 AHS (ABS 2012). The National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey (2012-13 NATSINPAS) used a 24-hour recall method similar to the 2011-12 NNPAS to collect data from respondents living in non-remote and remote areas of Australia (ABS 2013b). A total of 4,109 persons completed a 24-hour recall, and respondents who lived in non-remote areas only were invited to participate in a second 24-hour dietary recall on a non-consecutive day (ABS 2013b; ABS 2015a). Around 43% of these respondents living in non-remote areas completed a second recall (ABS 2015a), however these data were not used for the 2012-13 NATSINPAS publications produced by the ABS.

Relevant publications available on the ABS website from the 2012-13 NATSINPAS include:

- Nutrition Results – Food and Nutrients, 2012-13 (ABS 2015a)

- Consumption of Food Groups from the Australian Dietary Guidelines, 2012-13 (ABS 2016c)
- Consumption of Added Sugars, 2012-13 (ABS 2016d).

The ABS recently completed fieldwork for the 2021-2024 Intergenerational Health and Mental Health study, which includes a new NNPAS and NATSINPAS (ABS 2022b). Data from these surveys will be available in due course and will be used by FSANZ for dietary exposure assessment purposes once incorporated into Harvest.

4.2.2.2 New Zealand National Nutrition Surveys

FSANZ uses the results of the 2008/09 New Zealand Adult Nutrition Survey (2008/09 NZANS) and the 2002 New Zealand Children's National Nutrition Survey (2002 NZCNS) in its dietary exposure assessments for New Zealand.

The 2008/09 NZANS collected food and dietary supplement consumption data and other diet and health related measures, including biochemical measures from blood and urine samples, from 4,721 adults aged 15 years and above between October 2008 and October 2009 (University of Otago and Ministry of Health 2011). The survey intentionally over-sampled from Māori and Pacific populations in order to obtain robust estimates of dietary intake and nutritional status for these groups. A similar 24-hour recall methodology to the Australian NNPAS was used, with 25% of respondents completing a second 24-hour recall on a non-consecutive day (University of Otago and Ministry of Health 2011).

The 2002 NZCNS was conducted between February and December 2002 and collected food consumption data and other measures from 3,275 children aged 5-14 years (Ministry of Health 2003). Data on eating patterns, frequency of consumption, and consumption of dietary supplements were also recorded. A similar 24-hour recall methodology to the Australian NNPAS was used, with 15% of respondents completing a second 24-hour recall (Ministry of Health 2003).

4.2.2.3 Other nutrition surveys for individuals

FSANZ may use individual food consumption data from other relevant surveys when data from NNSs do not fit the purposes of an assessment. Australian and New Zealand NNSs to date have not included children under 2 years of age, for example, so individual food consumption data from surveys of infants and young children may be used by FSANZ to conduct dietary exposure assessments for this population sub-group.

4.2.2.3.1 Australian infants and young children

FSANZ has access to summary statistics for food consumption data collected from infants and toddlers at ages 9 and 18 months in the control arm of the Infant Feeding Activity and Nutrition Trial (INFANT) study, commenced in 2008 by researchers at Deakin University (Campbell et al. 2008). The study recruited first-time parents of 3 month old infants attending government-run parent groups in Local Government Areas within 60 km of the Deakin University campus in Burwood, Victoria. Primary carers completed 24-hour recalls over three non-consecutive days when their children were 9 and 18 months of age (Campbell et al. 2008; Campbell et al. 2013). Summary data has been used by FSANZ in relevant projects to assess dietary exposures in infants and young children.

FSANZ also has access to individual food consumption data for infants and toddlers at 4-7 months and 13-16 months of age who participated in two longitudinal studies: NOURISH and SAIDI (Daniels et al. 2009; Byrne et al. 2014). NOURISH is a randomised controlled trial study (FSANZ has access to control-arm data) of first-time mothers and their infants in Brisbane and Adelaide. SAIDI is an observational study of mothers and their infants in Adelaide and regional South Australia. Both studies commenced in 2008 and used the same food consumption collection

methodology: a 2-day food record and single 24-hour recall, scheduled with the aim of collecting two weekday and one weekend day of data on non-consecutive days, at each time point. FSANZ will add these data to *Harvest* in the future for use in relevant projects to assess dietary exposures in infants and young children.

4.2.2.3.2 New Zealand infants and young children

FSANZ has an agreement with the University of Otago for access to food consumption data for New Zealand infants and toddlers from the Baby-Led Introduction to SolidS study (BLISS) (Daniels et al. 2015), Eating Assessment in Toddlers study (EAT) (Mills et al. 2015), First Foods New Zealand and Young Foods New Zealand studies (Taylor et al. 2021; University of Otago 2021). FSANZ is adding these data to *Harvest* for use in relevant projects to assess dietary exposures in infants and young children.

Information on data sources for specific population sub-groups in New Zealand are summarised in a Ministry of Health report on food and nutrition monitoring (Ministry of Health 2006).

4.2.2.3.3 Commissioned surveys for Australia and New Zealand

Occasionally FSANZ may commission its own food consumption research through market research companies. Because of the high cost of such surveys, they are only done for specific chemicals, food groups and/or population groups. For example, in 1994 and 2003 FSANZ commissioned quantitative surveys of consumption patterns and dietary exposure to intense sweeteners in the Australian and New Zealand populations (National Food Authority 1995; FSANZ 2003). In 2010 FSANZ commissioned a qualitative survey of Australian and New Zealand adults and parents of children aged 3-14 years who consumed sports foods and drinks, to better understand the cognitive and behaviour approaches these consumers and carers take to purchasing and consuming the products (FSANZ 2010). The results of this survey informed a subsequent quantitative survey of sports food consumption by Australian and New Zealand adults (FSANZ 2013b).

4.2.3 Advantages and disadvantages of individual food consumption data for dietary exposure assessment

The advantages of food consumption data collected from individuals using either 24-hour recalls or food records for the estimation of dietary exposure include:

- dietary exposure for a wide range of food chemicals can be estimated if the consumption data are representative and comprehensive
- a range of consumption amounts for each food/food group can be taken into account
- the variety of foods for which consumption data are obtained is not restricted to a pre-determined list
- dietary exposures, and major food group contributors to dietary exposures for different population sub-groups can be estimated (where these sub-groups are included and identified in the scope of the survey)
- dietary exposure of consumers at low and high points of the distribution can be assessed
- individual data on other variables such as age, sex and anthropometry (e.g. weight, BMI) are often available alongside the food consumption data (section 4.3.1)
- scenarios of food chemical concentrations can be modelled to predict exposure under different risk management options.

The disadvantages of using food consumption data collected from individuals either using 24-hour recalls or food records for the estimation of dietary exposure include:

- the data are expensive to collect (although in Australia and New Zealand they are collected for other purposes)
- dietary exposure assessment analysis is more time consuming than use of data from screening techniques, requiring more technical expertise and an effective information technology system.

4.2.4 Limitations of individual food consumption data for dietary exposure assessment

Individual food consumption data, particularly data collected from NNSs, are the best data available to FSANZ for quantifying dietary exposure to a wide range of foods and food chemicals. There are however a number of important limitations associated with individual food consumption data related to study design and/or data collection methodology, and these must be considered when interpreting FSANZ's dietary exposure assessment results. FSANZ presents qualitative information about these limitations in dietary exposure assessment reports. Information related to the specific limitations associated with the most recent Australian and New Zealand NNSs are available in the methodology reports and user guides for the surveys (Ministry of Health 2003; University of Otago and Ministry of Health 2011; ABS 2013a; ABS 2013b).

Individual food consumption data do not necessarily provide a fully accurate representation of the type and amount of food that a survey respondent has eaten. For example, a respondent may not know the type of milk, oil or meat they have eaten, they may have eaten a mixed food that contained ingredients they were not aware of, or they may not know the volume of their cup of coffee. These measurement uncertainties introduce random error (Bailey et al. 2019). In all these cases, the survey managers will have made assumptions about what was actually eaten. Across a whole survey group, which is typically thousands of people, these assumptions may be of no significance in determining mean population food consumption.

The data collection methodology used can introduce systematic errors through measurement uncertainty, which may vary depending on the method used. For example, inaccurate assignment of serve size data can skew average estimates of consumption of the relevant food (e.g. if a cup of coffee was assigned a mass of 350 g instead of 250 g, average coffee consumption could be overestimated). Respondents may forget or not remember the type or quantity of food eaten, or whether a food was eaten at all. There may also be a tendency for respondents to over-estimate consumption of foods perceived as 'healthy', or change their diets as they are aware they are participating in a survey. The level of underreporting is usually assessed and reported as part of NNS documentation (University of Otago and Ministry of Health 2011; ABS 2013a).

4.2.4.1 Use of nutrition surveys for estimating food chemical exposure

NNSs are generally designed to estimate dietary intakes of nutrients and consumption of foods (broadly) at a population level. As a result, individual food consumption data from these surveys may have additional limitations when estimating dietary exposure to food chemicals other than nutrients. For example, NNSs generally do not distinguish between commercial fruit juices made from concentrate and not made from concentrate, because they are considered equivalent from a nutrient and food category perspective. However this would be a limitation if using the data to estimate dietary exposure to a contaminant or natural toxicant only found in juices not made from concentrate. Where relevant, FSANZ will use a conservative approach to ensure the dietary exposure is not underestimated.

4.2.4.2 Age of the data and changing consumption patterns

The 2011-12 NNPAS, 2012-13 NATSINPAS, 2002 NZCNS and 2008/09 NZANS are the most recent comprehensive sets of quantitative data on food consumption currently available to FSANZ.

Conducting dietary exposure assessments using these food consumption data provides the best estimate currently available of dietary exposure across Australian and New Zealand populations because they are national studies, across wide age ranges, of all foods and beverages consumed. These studies will continue to be used by FSANZ for a number of years to come until more up to date data become available.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Between NNSs, there can be significant changes to the Code to allow more innovation in the food industry, as well as changes to practices such as fortification. As a consequence, some of the foods that are currently available in the food supply were either not available or were not as commonly available at the time of the last NNS (e.g. plant-based dairy and meat alternatives). This can introduce extrapolation uncertainty into an exposure assessment (Kettler et al. 2015). For some dietary exposure assessments, these changes in the food supply will be particularly relevant and FSANZ will address these as far as possible in the assessment report, and identify where significant data limitations exist.

Where relevant, FSANZ will try to determine if there has been a major change in consumption patterns since the most recent NNS data were generated. Additional data on food consumption are sometimes available and these may help in the interpretation of food consumption and verify assessments carried out using the NNS on a case-by-case basis. Newer or other datasets may also be useful in determining the assumptions that could be made when conducting dietary exposure assessments with national surveys that may be some years old. Some of these data sources are set out in section 4.2.3.

For some product segments, the latest NNS data available may not be appropriate for use in a dietary exposure assessment because of major changes in consumption patterns since that time. In these cases, FSANZ may modify its modelling technique (e.g. through the selection of a similar food as a surrogate) or seek additional consumption data. The dietary exposure assessment reports may include a range of potential exposures based on different assumptions about current consumption patterns, in a similar manner to which lower bound and upper bound exposure estimates are produced when there is uncertainty about food chemical concentration levels.

4.2.4.3 Population statistics not individual consumption

The results of NNSs are suitable for describing the usual intake of groups of people, but these surveys were not designed, and cannot be used, to describe the usual intake of an individual (Rutishauser 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

4.2.4.4 Short term consumption data representing long term consumption

Section 5.5 discusses the difficulties of using one 24-hour food consumption record to represent a population's habitual or usual food consumption patterns. This section also discusses the approaches FSANZ has developed to account for these difficulties.

4.2.4.5 Reliability of estimates

Individual food consumption values provide a distribution from which summary statistics (such as mean consumption), the proportion of consumers and percentiles of food consumption and dietary exposure can be estimated. The reliability of these estimates depends on the number of individuals in the distribution and the variability in consumption amounts between individuals. Fewer individuals in a distribution and greater variability in consumption amounts between individuals are both associated with lower reliability of estimates.

There is no single consensus across the literature regarding the minimum number of observations required to reliably estimate percentiles of individual food consumption (EFSA 2011) and different regulatory agencies use different minimum numbers (FAO/WHO 2020a). To ensure percentile and other estimates are sufficiently robust, FSANZ assesses the individual food consumption data available on a case-by-case basis to ensure estimates are sufficiently robust to report. Generally, more extreme percentile estimates (e.g. 97.5th percentile) require a greater number of consumers to estimate with sufficient robustness compared with less extreme percentile estimates (e.g. 90th percentile).

FSANZ does not report any mean or percentile estimate where less than 10 individual food consumption values are available. Where FSANZ does report a percentile estimate, it is a real data point, consistent with international best practice (FAO/WHO 2020a). In cases where a percentile estimate does not fall naturally on a real data point, it is rounded up to the next real value.

There are some foods reported in the NNSs for which the number of people who ate the food (either from the whole population or from a certain age group) is too few to enable robust population estimates of consumption, and hence dietary exposure, to be produced. In these cases it may be necessary to select a similar, more widely consumed food, as a proxy. For example, peaches could be selected as a proxy food for nectarines.

4.2.5 Food consumption amounts inferred from other data sources

National data on food imports/exports or retail purchases can be used in combination with population figures to infer food consumption amounts per capita, and therefore to estimate average population consumption of foods or exposure to food chemicals. FSANZ rarely uses this approach for standards development purposes because NNS data are available, however inferred data can have significant cost and time advantages over consumption data collected from surveys or other studies and can provide useful supplemental information.

The advantages of using consumption data inferred from other data sources include:

- they may be readily available
- they can allow for inter country comparisons and monitoring major trends over time
- their use in dietary exposure estimates can assist with prioritising chemicals for further investigation
- they are not impacted by respondent errors such as inaccurate recall or intentional misreporting
- their use is cost effective.

The disadvantages of using consumption data inferred from other data sources include:

- mean dietary exposure for the whole population can be over- or under-estimated
- they rely on accurate demographic and food balance or purchase data

- they cannot be used to estimate the proportion of the population who are consumers of a food, or percentile estimates of consumption amounts (high consumption)
- they cannot be used for population sub-groups or 'non-average' consumption patterns and may underestimate dietary exposure for these groups
- consumption data inferred from food balance sheets are only suitable for dietary exposure estimates based on raw and semi-processed commodities, for example for contaminants, natural toxicants, and agricultural chemicals.

The two main types of inferred data used by FSANZ are food balance sheets and apparent consumption data.

4.2.5.1 Food balance sheets

At the national level, food balance sheets can provide per capita estimates of food availability in Australia and New Zealand. Produced by the FAO (2023a) and based on FAO Supply Utilization Account data, these food supply data sum national food production and imports, and deduct amounts for exports and non-food use; but do not account for household food stocks, food waste or intra-household food distribution (FAO 2023b). These figures therefore tend to over-estimate mean food consumption, and hence dietary exposure, by around 15% compared to individual survey estimates (FAO/WHO 2020a).

4.2.5.2 Apparent consumption data

The *Apparent Consumption of Selected Foodstuffs*, *Australia* (ACSF) collection is published by the Australian Bureau of Statistics (ABS) and provides annual figures on how much food is available for consumption (at the national and per capita levels) based on amounts purchased from the food retail sector (ABS 2024a). The food retail sector includes supermarkets as well as smaller outlets such as fresh food markets, bakeries, delis, butchers and convenience stores. Data on alcohol, and food availability from sources other than food retail outlets, such as restaurants, cafes, fast food outlets, wholesale outlets selling to institutions, home grown food and foraged food, are not captured in apparent consumption data. Food wastage and non-food uses are also not accounted for (ABS 2024a).

The ACSF collection was ceased after the 1989-99 financial year, then recommenced in 2018-19 with updated methodology using scanner data from major supermarkets and data from the most recent ABS Household Expenditure Survey rather than food balance sheet data. The expenditure ratios for each ACSF reference period are calibrated to reflect the changes in the proportion of specialised food retail purchased (from total food retail) by reference to the 2016 Household Economic Survey (ABS 2024b). From 2018-19 onwards, ACSF publications have reported apparent consumption per capita by broad food and beverage categories, 2013 Australian Dietary Guidelines food groups (data are mapped to AUSNUT foods), and for a range of nutrients including added and free sugars (ABS 2024a).

Due to the methodology listed above, apparent consumption data are not directly comparable to individual consumption data collected directly through national surveys and other studies. Apparent consumption data are a useful data source despite this limitation, and are used by FSANZ for validation purposes and to provide insights into changes in consumption trends, particularly those relevant to the food retail sector. One example of this is the increase in apparent consumption of plant-based dairy alternatives (such as soy and almond based beverages) captured in ACSF data between 2018-19 and 2020-21 (ABS 2024a).

In New Zealand, Statistics New Zealand conducts a Household Economic Survey every three years to provide data on expenditure patterns, income, social and demographic statistics, which includes data on food purchases (Stats NZ 2019).

4.3 Demographic and related data

There are two demographic variables available from NNSs that are used regularly in FSANZ dietary exposure assessments: age and sex. Ethnicity may sometimes be used for reporting purposes, although ethnicity does not necessarily determine food consumption patterns. NNS data on socioeconomic status, for example the SEIFA quintiles, are not routinely used as a separate variable in FSANZ's dietary exposure assessments, although there have been instances where this has been taken into account, such as the assessment of *Application A1090 Voluntary addition of Vitamin D to breakfast cereal* (FSANZ 2016b) and *Proposal P295 Consideration of mandatory fortification with folic acid* (FSANZ 2007b).

Geographic location is not typically used in FSANZ dietary exposure assessments, other than in separate reporting of exposures in Australia and New Zealand. As the same food standards apply in all states and territories of Australia and regions of New Zealand, it is most appropriate to produce national dietary exposure assessments. Regional variation in dietary exposure may be taken into account by using different concentrations of a chemical in different models while still using the same national consumption dataset. An example is the different iodine concentrations used for Australian and New Zealand foods used as part of the assessment of *Proposal P230 Iodine fortification* (FSANZ 2008b).

4.3.1 Body weight

Body weights are used for assessments where HBGVs are expressed on a body weight basis (FAO/WHO 2020a). In such cases either:

- individual dietary exposures or consumption amounts are adjusted by each individual respondents' body weight before derivation of statistics for a population's dietary exposure expressed on a body weight basis, or
- a mean population (or sub-population) body weight is calculated from all respondent body weights and used in the deterministic estimation of exposure on a body weight basis (see section 5.2.1).

Individual body weights were directly measured in the most recent Australian and New Zealand NNSs (Ministry of Health 2003; University of Otago and Ministry of Health 2011; ABS 2013a; ABS 2013b) but may be self-reported in other surveys.

4.3.2 Sampling and survey sample weights

In large, nationally representative surveys such as the Australian and New Zealand NNSs, it is rarely possible to obtain a sample of respondents that is truly representative of the overall population (response bias). Some population groups, such as younger and older adults, people who live in remote areas, are indigenous, are unemployed, are less educated or for whom English is not their first language, tend to be under-represented in relation to their true proportion in the overall population ('t Mannetje et al. 2011). In some surveys there may be deliberate over-sampling of a population sub-group in order to generate a statistically valid sample size in that group, for example in the New Zealand NNSs where Māori and Pacific people were over-sampled in proportion to their share of the New Zealand population to enable ethnic-specific analyses (Ministry of Health 2003; University of Otago and Ministry of Health 2011).

Survey sample weighting factors ('weights') are used to adjust survey data to better reflect the results that would have been obtained if a truly representative sample had been able to be

obtained. Large surveys will typically weight for a number of different features, such as age, sex, geographic distribution and ethnicity.

For the 2011-12 NNPAS and 2012-13 NATSINPAS, survey sample weights were based on the probability of being selected for the survey (ABS 2013a; ABS 2013b) with additional adjustments for sex, age and location. Season was included as a factor in the weighting for the 2011-12 NNPAS, with remoteness and ethnicity included in the weighting for the 2012-13 NATSINPAS (ABS 2013a; ABS 2013b). Two sets of sample weights are available for the 2011-12 NNPAS, and both are used by FSANZ; one set if just using day 1 food consumption data (n=12,153), the other set if using respondents with two days of consumption data (n=7,735).

Similarly for the 2002 NZCNS, survey sample weights were determined using the probability of selection for the survey, with adjustments for location, sex, age and ethnic group (Ministry of Health 2003).

For the 2008/09 NZANS, survey sample weights were developed using a calibrated weighting method which incorporated data on age, sex, ethnicity and population estimates from the 2006 Census (University of Otago and Ministry of Health 2011).

Use of survey sample weights are identified in dietary exposure assessment reports and are used to adjust the results of surveys to make population based estimations.

4.4 Other data used in dietary exposure assessments

There may be other data that FSANZ incorporates into its dietary exposure assessments. Sources may include market share or market uptake information for food products, or consumer research data on consumption behaviours and attitudes. For example, consumer insights tracker data were considered during the dietary intake/exposure assessment for *Application A1269 Cultured Quail as a Novel Food* (FSANZ 2023a). Generally these additional data either assist with forming the assumptions that are used in setting up a dietary model, or with the interpretation of the assessment results.

4.4.1 Market share or uptake data

Actual market share or projected market uptake data for products that contain, or are proposed to contain, a food chemical are useful for some dietary exposure assessments (FAO/WHO 2020a). Information on the specific food products most likely to contain a chemical such as a food additive, nutrient or a novel food, is also useful. Market share or uptake data may be derived from food industry reports, branded food databases, directly from the food industry, Applications, or from observation.

FSANZ uses this type of information to:

- more clearly identify the foods that are likely to contain the food chemical of interest
- adjust chemical concentration levels to take into account the likely long term mean chemical level in a food category
- more clearly identify the population groups that are most likely to consume the foods containing the chemical of interest
- determine if there has been a significant change in the market for a product category since the NNS data were collected
- develop scenarios of possible market uptakes that better reflect likely long term consumption patterns for different food categories

- validate consumption data sets used
- interpret the results of an exposure assessment.

Section 5.6 contains more detail about conducting a market weighted dietary exposure assessment.

4.4.2 Consumer research data

Data from research into consumer attitudes and behaviours can be useful in some dietary exposure assessments. As with market share information, consumer research can help to establish modelling scenarios and to interpret dietary exposure assessment results.

In addition to some of the uses identified above, consumer research data can also help to:

- identify reasons for selection or avoidance of certain foods
- identify consumer awareness of new food technologies or novel foods
- identify whether consumers will add a new food to their diets or replace an existing food from their diet if they choose to consume a new type of food
- assess whether or not a group of consumers will be loyal to a particular brand or will purchase from a range of like brands, some of which may not contain the chemical in question.

Consumer research data may be from domestic or international sources, however data relating to Australia and New Zealand are the most relevant.

Depending on the findings of any relevant consumer research available, FSANZ may conduct an estimate of dietary exposure based on predicted consumer behaviour towards the food in question. This could, for example, include an assumption that there is a group of consumers who always choose a particular brand of a food containing the food chemical in question, such as always choosing a particular brand of fortified breakfast cereal or flavoured water-based beverage.

Section 5.7 contains more information about conducting a consumer behaviour dietary exposure assessment. Further information on consumer research conducted by FSANZ can be found on the FSANZ website (FSANZ 2024).

4.4.3 Human biomonitoring data

As part of the 2011-13 AHS, a National Health Measures Survey (NHMS) and an Aboriginal and Torres Strait Islander Health Measures Survey (ATSIHMS) were also undertaken. These were the biomedical components of the AHS. Across Australia, around 11,000 respondents aged 5 years and over in the NHMS, and around 3,300 adults respondents in the ATSIHMS voluntarily provided blood and/or urine samples, which were tested for a range of chronic disease and nutrition biomarkers (ABS 2013c; ABS 2014a)). FSANZ has used results from the NHMS in dietary exposure assessments (e.g. vitamin D (FSANZ 2016b)).

4.5 Food classification systems

NNSs have traditionally classified foods into food groups that were similar to food selection guide food groupings, as these groups were useful for reporting sources of nutrients in population diets. In a NNS classification system each food reported as consumed is given a unique food code. The survey food codes are organised in a hierarchical format based on food groupings. Figure 5 shows an example of a food classification system from the 2011-12 NNPAS used for nutrient intake

assessments for Australia. In this example, each survey food (e.g. Barley, pearl, uncooked) is given an 8 digit code. The survey foods are then grouped into 5, 3 and 2 digit food groups accordingly (FSANZ 2023e).

12 = Cereals and cereal products
  121 = Flours and other cereal grains and starches
    12101 = Grains (other than rice)
      12101001 = Barley, pearl, uncooked
      12101002 = Barley, pearl, cooked in water, no added salt or fat

Figure 5: An example of the food classification system for the 2011-12 NNPAS (FSANZ 2023e)

Nutrient intake assessments are conducted based on the consumption of individual foods reported in the NNSs. As each survey food reported is assigned a unique nutrient profile from a survey specific food composition database no further classification system is required for the intake assessment.

For the purpose of dietary exposure assessments for other food chemicals, the way specific foods are defined and classified into food groups is very important, and should be appropriate for each type of food chemical being assessed. Permissions in the Code for food chemicals are generally assigned to a group of similar foods and therefore the myriad of foods reported as consumed in the NNS must be assigned to the correct food groups to ensure food concentrations are assigned appropriately and the dietary exposure assessment is as accurate as possible. In *Harvest,* foods are grouped into categories appropriate for the assessment of processed foods or raw commodity groups, or may be used ungrouped.

4.5.1 Food additive classification system

For the dietary exposure assessment of food chemicals such as food additives or novel foods, foods are classified into groups according to potential or permitted additive use. The classification system used by FSANZ has been adapted from the Codex General Standard for Food Additives (GSFA) (FAO/WHO 2023c) and is used in Schedule 15 *Substances that can be used as food additives* of the Code (Australian Government 2021). An example of some of the food group classes is provided in Figure 6.

1	Dairy products (excluding butter and fats)
1.1	Liquid milk and liquid milk based drinks
1.1.1	Liquid milk (including buttermilk)
1.1.1.1	Liquid milk to which phytosterols, phytostanols or their esters have been added
2	Edible oils and oil emulsions
2.1	Edible oils essentially free of water
4	Fruits and vegetables (including fungi, nuts, seeds, herbs and spices)
4.1	Unprocessed fruits and vegetables
4.3	Processed fruits and vegetables

Figure 6: An example of the food group classes from Schedule 15 of the Australia New Zealand Food Standards Code (Australian Government 2021)[12]

[12] Sourced from the Federal Register of Legislation at 12 September 2023. For the latest information on Australian Government law please go to https://www.legislation.gov.au.

4.5.2 Raw commodity classification system

For the assessment of dietary exposure to agvet chemical residues, contaminants or natural toxicants, it is most appropriate for foods to be classified into raw commodity groupings. The classification system used by FSANZ is based on the Codex food category system (FAO/WHO 2023b) as used in Schedule 22 *Foods and classes of foods* of the Code (Australian Government 2022).

Use of agvet chemicals is restricted. A chemical can be registered for single commodities within a given food group, a sub-group of commodities or at a major group level. For example, a pesticide may be registered for use on pears but not on apples; in this case, dietary exposure assessments would include the single commodities not the whole food group. Alternatively an MRL may apply to the sub-group 'Lemons and limes' therefore consumption of all commodities captured in that sub-group (lemons, limes, kumquats and citron) need to be included in the dietary exposure assessment. The capability to conduct dietary exposure assessments using major groups as a whole also exists, as does using a combination of major groups and individual commodities.

An example of some of the raw commodity classification codes and food group descriptions used by FSANZ is shown in Figure 7.

```
FB Berries and other small fruit (group)
     Low growing berries (sub-group)
          FB0277  Cloudberry
          FB0265  Cranberry
          FB0275  Strawberry

MM Meat (mammalian) (group)
          MM0812  Cattle meat
          MM0817  Kangaroo meat
          MM0822  Sheep meat
```

Figure 7: An example of the codes and food group descriptors from the FSANZ raw commodity classification system

4.5.3 Mapping

As a consequence of needing to conduct dietary exposure assessments based on food classification systems such as those described above, a major step in conducting dietary exposure assessments is mapping (also called 'translating' or 'matching') the individual foods consumed to the food groups in the food classification systems outlined above (FAO/WHO 2020a). For example, green apples and red apples, peeled or unpeeled, could be mapped to the raw commodity code for apples; cheddar cheese, mozzarella cheese and all other types of ripened cheeses could be grouped in the single food additive class for cheese and cheese products. Once mapping is completed, a single food chemical concentration value for a group of foods (e.g. apples, or cheese and cheese products) can be assigned to the classification and all foods that are matched to this group are assigned that concentration in the dietary exposure calculation.

Although foods are appropriately pre-grouped in *Harvest* for the majority of food additive and raw commodity exposure assessments, at times different mapping may be required to meet the needs of a specific exposure assessment, for example, to distinguish sugar sweetened products from those containing intense sweeteners. Mapping is also a key process in the dietary exposure assessments for the ATDS (see section 4.1.1.5.1).

4.5.4 Recipes

Many individual foods from a NNS, such as mixed foods, do not directly match one of the food additive or raw commodity classification codes used in dietary exposure assessments. Recipes are used in *Harvest* for mixed foods to disaggregate the food into component ingredients (FAO/WHO 2020a). Separate recipes are derived to apportion ingredients under the food additive and raw commodities classifications codes. For example, a mixed dish of vegetables with white sauce may be apportioned between major ingredients such as common vegetables and white sauce for a food additive recipe, but split up further into individual vegetables, butter, milk and flour for a raw commodity recipe. These recipes are developed taking into account common food preparation and processing practices, but are an approximation of what the actual composition of a mixed food might be.

As each NNS food is assigned specific nutrient values as part of the NNS itself, recipes are not needed for nutrient intake assessments.

4.5.5 Hydration and raw equivalence factors

Hydration and raw equivalence factors[13] are applied to some foods in *Harvest* to convert the amount of food consumed in the NNS to the equivalent amount of the food in the form to which a food chemical permission is given (e.g. processed foods as consumed for food additives, raw commodities for contaminants and pesticide residues). Factors are only applied to individual foods as consumed on the day of the nutrition survey, and not major food groups or mixed foods. For example, an amount of cordial as syrup reported in the NNS is converted using a hydration factor to an amount of prepared cordial for a food additive assessment, or an amount of cooked meat reported in the NNS is converted to raw meat using a raw equivalence factor for an assessment for a contaminant.

Conversion factors of these kinds are based on many different sources of data depending on the food including instructions for product preparation, food composition information, weight change factors, processing information, fat content, or protein content.

4.6 Health-based guidance values (HBGVs)

The final step in the risk assessment framework, risk characterisation, is a qualitative or quantitative estimation of the probability of occurrence and severity of known or potential adverse effects in a given population. Risk characterisation is based on the preceding steps of hazard identification, hazard characterisation and dietary exposure assessment (FSANZ 2013a). FSANZ dietary exposure assessment reports generally include a comparison of dietary exposure against the relevant HBGV as part of this risk characterisation. Further information on how HBGVs are set by JECFA and JMPR is described in *Chapter 5 of EHC 240* (FAO/WHO 2020b).

4.6.1 Food chemicals with HBGVs

Different types of food chemicals have different types of HBGVs. The HBGVs that FSANZ uses for dietary exposure assessment and risk characterisation purposes are outlined below:

- For food additives and residues of agvet chemicals in food, the HBGV for chemicals that may have a potential for adverse effects on a chronic or long term basis is the *acceptable daily intake (ADI)*. “The ADI is an estimate of the amount of a chemical in food or drinking water, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable risk to the consumer” (FAO/WHO 2009a p. A-2). ADIs established by JECFA or

[13] Also called adjustment factors (FAO/WHO 2020).

JMPR are provided numerically as a range of acceptability from 0 to an upper limit, expressed to one significant figure (FAO/WHO 2020b).

- For veterinary chemicals with an antimicrobial action, a microbiological ADI or ARfD may be established if the residues in food adversely affect the intestinal microflora of consumers (APVMA 2014; Boobis et al. 2017; FAO/WHO 2020b).
- For contaminants and natural toxicants, the HBGVs used to indicate the safe level of chronic exposure is the so-called *tolerable intake*, which can be calculated on a daily (TDI), weekly (TWI) or monthly (TMI) basis. The tolerable intake is defined in the same way as the acceptable intake for food additives but use of the term 'tolerable' indicates that contaminants and natural toxicants are not deliberately added to foods (FAO/WHO 2009a). Where there has been a lack of data and new data may result in a change to these levels, tolerable intakes may be described as '*provisional'* (e.g. PTDI). However as HBGVs can be revised with new data, it is recommended that term 'provisional' is no longer used *(*FAO/WHO 2020b).
- For chemicals with potential for adverse effects on an acute or short term basis, an *acute reference dose (ARfD)* may also be determined. The ARfD is "the estimate of the amount of a substance in food or drinking water, expressed on a body weight basis, that can be ingested in a period of 24 hours or less, without appreciable health risk to the consumer" (FAO/WHO 2009ap. A-3). Depending on its hazard profile, a chemical may have an ARfD as well as a chronic HBGV (e.g. ADI). ARfDs are generally set only for some agvet chemicals and contaminants, but could also be set for any other food chemical with a potential for acute adverse effects at the levels that could be found in foods.
- There are several HBGVs for nutrients, also called Nutrient Reference Values (NRVs), established for the Australian and New Zealand Populations by the NHMRC, Australian Government Department of Health and Ageing and the New Zealand Ministry of Health (2006). The NRVs are defined as the "amount of nutrients required on an average daily basis for adequate physiological function and prevention of deficiency disease or chronic disease prevention" (NHMRC et al. 2006 p. 8). NRVs apply to chronic nutrient intakes. The definitions for each NRV are below (NHMRC et al. 2006 pp. 1-3):
    - *"Estimated average requirement (EAR)*: a daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.[14]
    - *Adequate intake (AI)*: the average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
    - *Upper level of intake (UL)*: the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.
    - *Acceptable macronutrient distribution range (AMDR)*: an estimate of the range of intake for each macronutrient for individuals (expressed as per cent contribution to energy) which would allow for an adequate intake of all the other nutrients whilst maximising general health outcome.
    - *Suggested dietary target (SDT)*: a daily average intake from food and beverages for certain nutrients that may help in prevention of chronic disease".

Some chemicals that are recognised as contaminants are also nutrients (e.g. selenium and copper). For these contaminants a tolerable intake may exist as well as an NRV (FSANZ 2007a). In these cases, the NRV is usually used for risk characterisation purposes. FSANZ may use an AI for risk characterisation purposes where an EAR could not be established and where it is appropriate for the assessment being conducted. Further information on the use of AI for risk

14 This is the measure of population adequacy that FSANZ uses most often in nutrient risk assessments.

characterisation purposes can be found in the *Nutrient Reference Values for Australia and New Zealand* document (NHMRC et al. 2006). Some NRVs are established for naturally occurring sources, synthetic or added sources (e.g. UL for folic acid). Where there are different sources, nutrient intakes may be expressed in the form of 'equivalents' from all sources (e.g. retinol equivalents; dietary folate equivalents) or for dietary supplemental forms only (e.g. ULs for magnesium). FSANZ ensures the appropriate form of the nutrient is used to estimate intake for comparison to the NRV.

4.6.2 Food chemicals with no HBGV

For some food chemicals assessed by FSANZ, no formal HBGV has been established, for example for some food additives, processing aids, contaminants and novel foods. This could be because there is insufficient data to derive a HBGV or the chemical is a mutagenic or genotoxic carcinogen (FAO/WHO 2020b).

For some of these chemicals a margin of exposure (MOE) approach may be used to provide an estimate of relative risk (see Equation 3) (FAO/WHO 2020b). The MOE is the ratio of the no-observed-adverse-effect-level (NOAEL) or benchmark dose (BMD) derived from toxicological studies to the estimated dietary exposure (FAO/WHO 2009a). The NOAEL or BMD may also be called the 'point of departure' in a risk assessment (FAO/WHO 2020b).

$$\textbf{MOE} = \frac{\text{NOAEL or BMD}}{\text{Dietary exposure}}$$

Equation 3: Margin of Exposure equation

For other food chemicals and ingredients, the estimated dietary exposure is sometimes compared to a health effect or dose level from a safety or efficacy study e.g. minimal effect doses for non-dioxin-like polychlorinated biphenyls (FAO/WHO 2016). Alternatively, it may not be possible to complete a risk characterisation step, in which case the FSANZ risk assessment report will omit this component or describe why it may not be relevant in a certain case (e.g. some enzyme processing aid assessments).

Dietary exposure estimates for chemicals without HBGVs may still be useful. For example, they may be used to:

- identify key foods/food groups contributing to exposure
- compare the relative importance of exposure via food with other exposure routes when determining risk management options
- compare exposures estimated by FSANZ to those in other studies
- assist in determining if some form of risk management is needed (e.g. industry reformulation, maximum levels in the Code, or codes of practice in the case of food processing contaminants).

Another example of a chemical with no HBGV may be where a food additive or processing aid has been assigned an 'ADI not specified'. This HBGV is non-numerical and is usually assigned for food additives and processing aids that have very low potential for adverse health effects. In these cases, FSANZ typically decides there is no need to undertake a dietary exposure assessment.

5 CONDUCTING A DIETARY EXPOSURE ASSESSMENT

In principle, dietary exposure assessments are conducted for most proposed changes to the Code relating to levels of food chemicals. In practice the complexity of, and need for, the assessment will vary. Before beginning a dietary exposure assessment there are a number of considerations including:

- Can a dietary exposure assessment address the issues identified and/or answer the regulatory or risk assessment question(s) being posed?
- What type of chemical is being assessed (e.g. additive, nutrient etc) and what are the toxicological endpoints?
- What is the nature of the hazard and therefore what modelling approach should be used?
- Are there any particular target groups or groups that could be vulnerable to the effects of this food chemical (if any)?
- Are there sufficient suitable data available (consumption, concentration, additional qualifying information) to perform an assessment?
- Would a simplified screening technique be sufficient?
- In what format are the results required?

Assuming the answer to the first question is yes, the answers to the remaining questions will determine the type of dietary exposure assessment required and the methodology that will be used.

5.1 Tiered or stepwise approach to dietary exposure assessment

As described in Chapter 3, it is desirable to make the best estimate of dietary exposure for the assessment task at hand, using the best available data and world's best practice methodology. However the selected dietary exposure assessment techniques should be no more complex than is necessary to answer the regulatory or risk assessment questions. A tiered or stepwise approach to dietary exposure assessment makes best use of the available resources, in terms of staff resources and data availability, and matches them to the requirements of the task at hand.

Modelling techniques available to use in a tiered approach, range from screening techniques such as the budget method, through to deterministic and probabilistic modelling methods. Each of these methods are outlined in section 5.2 below. The tiered approach as used by FSANZ and other international regulatory agencies is illustrated in Figure 8. Moving from a 'broad brush' first estimate to a more refined estimate, data and resource requirements increase (FAO/WHO 2020a).

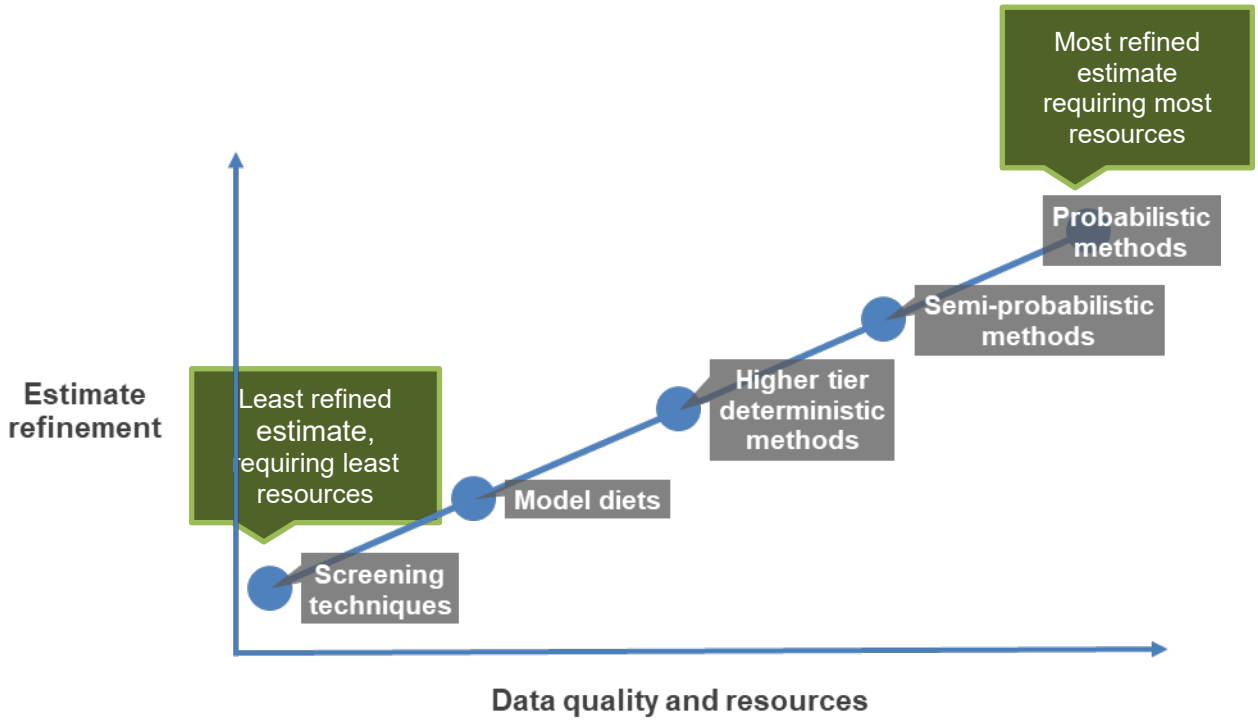

Figure 8: The tiered approach to conducting dietary exposure assessments at FSANZ

In a tiered approach to dietary exposure assessment, the initial assessment will tend to be very conservative, that is protective of the population, and often used as part of a screening process. More realistic deterministic, semi-probabilistic[15] or probabilistic dietary exposure assessments using food consumption data for individuals may be necessary if results of screening techniques or model diets are not conclusive or indicate that estimated dietary exposure to a food chemical may exceed the relevant HBGV. Alternatively, more refined dietary exposure assessment methods may be used in the first instance if the data are available and/or an accurate estimate of dietary exposure is required.

These more refined estimates can result from using improved or more detailed consumption data, improved or more detailed concentration data, more sophisticated methodologies or modelling techniques, or a combination of these. The usual approach at FSANZ involves the use of individual dietary records derived from NNSs. These individual consumption records may be used in a deterministic assessment, as typically occurs for agvet chemical residues, or can be incorporated into a semi-probabilistic approach using *Harvest*. It is important to note that whether FSANZ uses a deterministic, semi-probabilistic or probabilistic exposure assessment technique, the same underlying consumption and food chemical concentration data will be used as a starting point.

The method or technique used for each dietary exposure assessment is clearly outlined in risk assessment reports prepared by FSANZ.

5.2 Major types of dietary exposure assessments used by FSANZ

There are many different ways a dietary exposure assessment can be conducted. These approaches are divided into three main types:

- deterministic methods (including screening techniques and model diets)
- semi-probabilistic methods
- probabilistic methods.

15 Also called refined deterministic (FAO/WHO 2020).

These approaches, including advantages and disadvantages, are described in more detail in *Chapter 6 of EHC 240* (FAO/WHO 2020a). The approaches used by FSANZ are outlined below, in approximate order of increasing complexity.

5.2.1 Deterministic dietary exposure assessments

Regardless of technique, all deterministic methods use single point food consumption, food chemical concentration and body weight data in the calculations, however each of the methods have different purposes and are used in different ways. As a first tier assessment, screening techniques use very conservative assumptions whereas higher tier deterministic assessments include data that enable more realistic estimates of exposure.

5.2.1.1 Screening techniques

Screening techniques are used by FSANZ to determine if there are public health and safety issues based on conservative assumptions or not, and if there are, to identify chemicals for which more detailed exposure assessments are warranted (FAO/WHO 2020a). This 'priority setting' role is one of the main uses of screening techniques at FSANZ, for example in developing a risk matrix to allow rapid identification of foods or food chemicals that may present a significant risk (e.g. risks from a newly identified contaminant). The other main use of screening techniques at FSANZ is to provide an early indication of whether permissions sought for a proposed new food additive or processing aid are likely to exceed the relevant ADI or point of departure. Screening techniques are not intended to estimate 'true' dietary exposure.

When deciding when to use a screening technique as the first part of a tiered approach to a dietary exposure assessment, FSANZ considers:

- the nature of the hazard posed by the chemical (chronic or acute)
- if a more accurate estimate of exposure is needed
- the type of chemical
- if a HBGV or point of departure (e.g. NOAEL, BMD) exists
- if a screening technique or refined DEA have recently been conducted for the chemical.

Screening techniques are quick and easy to use, requiring the least amount of resources to answer the regulatory or risk assessment questions. As the most protective approach, the technique chosen should overestimate long term dietary exposure of high consumers using conservative, but also realistic assumptions for comparison with a HBGV (FAO/WHO 2020a). A summary of the screening techniques used by FSANZ for food additives, processing aids, contaminants and natural toxicants is in Table 4. Screening techniques are generally not used by FSANZ for nutrients, nutritive substances, or novel foods as more accurate estimations of intake are often required and there may not always be a HBGV.

Table 4: Summary of screening techniques used by FSANZ

Food chemical	Food additives	Processing aid	Contaminants and natural toxicants
Screening techniques	Poundage data *(5.2.1.1.1)* Budget method *(5.2.1.1.2)* Reverse budget method *(5.2.1.1.3)* High consumer model *(5.2.1.1.4)* Added sugar replacement model *(5.2.1.1.5)* Theoretical Maximum Allowable Level (TMAL) *(5.2.1.1.6)*	Budget method *(5.2.1.1.2)* Reverse budget method *(5.2.1.1.3)*	Theoretical Maximum Allowable Level (TMAL) *(5.2.1.1.6)* Back calculation method *(5.2.1.1.7)*

5.2.1.1.1 Poundage data

With this technique, per capita availability of a food or food additive is estimated based on imports as well as any domestic production and exports, and can be adjusted to account for the fact that only a certain proportion of the population may consume the food or food additive (including flavouring agents). The estimate is usually produced over a one year time period, and can be estimated on a body weight basis if applicable (FAO/WHO 2020a; Bi 2023).

There is considerable uncertainty associated with any exposure estimates based on these data as annual production, exports or imports can vary markedly, non-food use, food waste, and food loss may not be accounted for, additive levels in imported foods cannot be assessed, and individual consumption/exposure cannot be estimated (FAO/WHO 2020a; Bi 2023). Although per capita dietary exposures based on poundage data may be over-estimated, the dietary exposure of a consumer who regularly consumes a certain brand or type of food may be underestimated using this method (FAO/WHO 2020a). This method is infrequently used at FSANZ as FSANZ is able to use individual consumption data for its dietary exposure assessments. Further information on the uses and limitations of poundage data can be found in *Chapter 6 of EHC 240* (FAO/WHO 2020a).

5.2.1.1.2 Budget method

The budget method is a valid screening tool for estimating the *theoretical maximum daily intake* (TMDI) of a food additive (Douglass et al. 1997) which can then be compared to an ADI, NOAEL or BMD to estimate a margin of exposure (MOE) for risk characterisation purposes. Although initially developed for food additives, the budget method is also used by international regulatory bodies and JECFA (FAO/WHO 2021a) for processing aids such as enzymes.

The budget method calculation is based on the following conservative assumptions:

- food consumption is the same as physiological solid food (including milk) and liquid requirements (0.05 kg/kg bw/day for solid food, 0.1 L/kg bw/day for liquids) for a 1-2 year old child given their high food consumption amounts per kilogram of body weight and high energy requirements due to growth (Hansen 1979; Douglass et al. 1997)
- the maximum proposed or reported food additive/processing aid concentrations in solid foods and non-milk beverages

- the proportion of solid foods and non-milk beverages that may contain the food additive/processing aid
- that all the food additive/processing aid remains in the final food or beverage.

Separate calculations are performed for the solid (including milk) portion of the diet and the non-milk beverage portion of the diet, with the TMDI for each portion summed as per Equation 4.

Total TMDI (mg/kg bw/day) =

(0.05 kg/kg body weight/day x maximum concentration in solid foods x % solid foods that may contain the food additive/processing aid)
+
(0.1 L/kg body weight/day x maximum concentration in non-milk beverages x % non-milk beverages that may contain the food additive/processing aid)

Equation 4: Budget method calculation (Douglass et al. 1997)

FSANZ may further refine the budget method calculations by including:

- actual solid food and non-milk beverage consumption data from national surveys
- if the food additive/processing aid is added to a raw material (not the final food):
    - a raw material to final food ratio
    - the proportion of solid foods and non-milk beverages that may contain the raw material.

FSANZ uses the budget method primarily for the assessment of processing aids and food additives (e.g. *Proposal P150* (FSANZ 1998)) Further information on the uses and advantages of the budget method can be found in *Chapter 6 of EHC 240* (FAO/WHO 2020a).

5.2.1.1.3 Reverse budget method

The reverse budget method (see Equation 5) calculates the amount of food that it is necessary to consume in order for the ADI not to be exceeded, assuming the maximum level of use, but can only be used for food chemicals used or occurring in a few foods (FAO/WHO 2020a). An assessment is made as to whether consumption of this amount of food is likely or not, by comparison to actual food consumption data. If the amount of food that may be consumed before the ADI is exceeded is lower than expected consumption, then more accurate dietary exposure estimates are required (FAO/WHO 2020a). The reverse budget method was used by FSANZ in the assessment of food additives for *Proposal 150* and for *A396 Erythrosine in preserved cherries* (FSANZ 1998; FSANZ 2000).

$$\textbf{Amount of food (kg)} = \frac{\text{ADI (mg/kg) x mean population body weight (kg)}}{\text{MPL (mg/kg food)}}$$

Equation 5: Reverse budget method

5.2.1.1.4 High consumer model

Food standards should protect those consumers who habitually eat large amounts of one or more particular foods or groups of foods, or have a dietary exposure at the high end of the exposure distribution (high consumers). The high consumer model assesses the potential for a high consumer of specific foods or food groups containing the food chemical of interest to have exposures that exceed a HBGV for a given food chemical. This method is often used by FSANZ as a screening tool (such as in *Proposal P150* (FSANZ 1998)) or when only summary population consumption data are available (FAO/WHO 2020a). Note that this screening method (based on a

single high food consumption amount for the population and mean consumption amounts for all other foods) is different to estimating a high exposure for consumers of a chemical which is based on actual consumption amounts for every individual (see section 5.5.1).

The high consumer model identifies one or two representative foods or food groups[16] which are likely to make the greatest contribution to total dietary exposure for that food chemical. High (e.g. 90th percentile) chronic food consumption amounts for these foods from the NNS are multiplied either by the food chemical MPL,[17] or mean/median (residue) level from analytical survey or manufacturer use data, and these exposures are added to the estimated mean chronic dietary exposure from all other foods, see Equation 6. The equation may be further refined by incorporating information on market share, processing or food preparation.

High consumer dietary exposure (mg/kg body weight/day or mg/day) =

∑(highest consumer food chemical exposures from one or two representative foods) +
mean population food chemical exposures from all other foods

Where:
highest consumer food chemical exposures from one or two representative foods = 90th percentile chronic consumption for each food x mean or median food chemical level for each food.

And:
mean population food chemical exposures from other foods = mean chronic respondent consumption of food x mean or median food chemical level for each food.

Equation 6: High consumer model equation

The assumption used in this high consumer model is based on work in the United Kingdom that determined “an individual might be a high level consumer of two food categories and would be an average consumer of the remaining other groups” (EFSA 2011 p. 21). However, this assumption is very dependent on how foods are described; the narrower the food descriptions (towards specific items rather than major food groups) the more likely that more than two foods could be consumed in large quantities (EFSA 2011), thereby making the high consumer model invalid. A further assumption of this model is that consumption of each food category is independent of other food categories which may not always be the case (EFSA 2011).

The Global Estimate of Chronic Dietary Exposure (GECDE) is an example of a high consumer model used by JECFA and JMPR for chronic dietary exposure assessments of veterinary drug residues and pesticide residues respectively (FAO/WHO 2020a). In the application of this model, the highest exposure (97.5th percentile) from one food category plus consumption of all other food groups containing the chemical of interest at the population average is used as it is assumed that an individual would be a high consumer of one food group only (Boobis et al. 2017). Further refinements to the method now include using a highest reliable percentile consumption value (not always the 97.5th percentile) based on the consumption data available (Arcella et al. 2019). Further information on the uses and advantages of the high consumer model, including the GECDE can be found in *Chapter 6 of EHC 240* (FAO/WHO 2020a).

[16] The use of two representative foods or food groups will result in a more conservative estimate than the use of one representative food or food group.

[17] A higher concentration level (e.g. MPL or proposed maximum level) may be used for consumer behaviour or pre-regulation screening assessments.

5.2.1.1.5 Added sugar replacement model

The added sugar replacement model is used to identify intense sweeteners which may need a more refined dietary exposure assessment by assuming that all added sugars in foods and beverages in the diet are replaced with an individual intense sweetener. Usual intakes of added sugar at the mean and 90th percentile are replaced with an amount of each intense sweetener of interest using the relative sweetness (compared to sucrose) of each to determine dietary exposure to the sweetener (refer to section 5.5.2.2 for derivation of usual intakes). Each value is divided by the mean population body weight and compared to the relevant ADI. This model was used by FSANZ together with MPI in New Zealand as a screening technique in a review of intense sweeteners permitted in the Code (FSANZ 2023l).

5.2.1.1.6 Theoretical maximum allowable level

The theoretical maximum allowable level (TMAL) for a specific commodity or food group is the concentration of a food chemical which a high consumer of that commodity or food group would need to be exposed to, in order to have a dietary exposure equal to, but not exceeding, the HBGV (FAO/WHO 2020a). The calculation can take into account contributions to total dietary exposure from all other foods consumed at a population average level, if applicable to the food chemical in question and if that information is available. TMALs can be calculated for all food chemicals, but are mainly used for contaminants and natural toxicants.

The TMAL is used in food chemical risk analysis:

- where there is no established ML
- when permissions for a food additive are GMP
- when the ML is proposed to be removed or revised
- for development of contaminant concentration thresholds
- to put analytical concentrations into context.

The TMAL is generally calculated using the mean population body weight and a high consumption amount (e.g. 90th percentile) for consumers of the commodity or food group of interest (see Equation 7). Where the TMAL is being estimated for consumers of an occasionally consumed food, the median consumption amount is used, as it better reflects a high level of consumption over a long period of time. The frequency of food consumption can be determined using food frequency questionnaires, e.g. from the 1995 Australian National Nutrition Survey as used in FSANZ's assessment of metal contaminants in food (FSANZ 1999). Foods that are consumed less than once a week by 75% of the population or more are considered to be 'occasionally' consumed (FSANZ 1999). For contaminants with significant exposure from non-dietary sources, for example lead, potential exposure from these sources should also be considered when comparing total potential exposure to the HBGV.

TMAL =

$$\frac{\text{(HBGV (units/kg bw) – mean respondent exposure from all other foods (units/kg bw))} \times \text{mean population body weight (kg)}}{90^{th} \text{ percentile consumption amount for commodity or food group of interest (kg)}}$$

Equation 7: TMAL equation

5.2.1.1.7 Back calculation method

A method described as a 'back calculation' is similar to the TMAL, however focussing on a different part of the dietary exposure assessment equation (see Equation 8). This method is generally used to assist in making risk management decisions on the amount of a food that can be consumed before the HBGV is exceeded, based on a known concentration of a chemical in the food (similar to a reverse budget method calculation for food additives and processing aids) (FAO/WHO 2020a). This method can also take into account the level of dietary exposure from all other foods. FSANZ used this method when determining the amount of fish that can be consumed by various population groups in order to manage dietary exposure to mercury (FSANZ 2020b).

Amount of food (kg) =

$$\frac{\text{(HBGV (units/kg bw) – mean respondent exposure from all other foods (units/kg bw))} \times \text{mean population body weight (kg)}}{\text{concentration of chemical in the food (units/kg food)}}$$

Equation 8: Back calculation equation

5.2.1.2 Model diets

Model diets are defined as:

> *"A type of screening method used in dietary exposure assessments that assumes fixed default consumption levels, usually for categories of foods and beverages. Model diets can be based on hypothetical consumption data assuming maximum consumption amounts for broad food groups (e.g. the budget method) or can be derived from national food supply or consumption data..."* (FAO/WHO 2009a p. A-24).

FSANZ may construct a model diet (sometimes referred to as a 'simulated' or 'theoretical' diet) to conduct a dietary exposure assessment where no individual food consumption data are available (e.g. for infants and young children).

Model diets are also used at the international level for estimating chronic or long term food chemical exposure for individual countries or clusters (groups of countries). Examples include the WHO Global Environment Monitoring System-Food Contamination Monitoring and Assessment Programme (GEMS/Food) cluster diets (Sy et al. 2013; WHO 2023a) and the model diet that was used by JECFA for exposure assessments of veterinary drug residues (FAO/WHO 2009b).

Further information about model diets is available in *Chapter 6 of EHC 240* (FAO/WHO 2009b; FAO/WHO 2020a).

5.2.1.2.1 FSANZ model diet for children aged less than 2 years

There are no data available from the 2011-12 NNPAS for children less than 2 years of age and from the 2002 NZCNS for children less than 5 years of age. Therefore FSANZ constructs model diets to prepare dietary exposure estimates for very young children. This is often done for a three month old infant, a nine-month old infant and/or a one year old child. These model diets are constructed using recommended energy intakes defined by the WHO, usually for boys at the 50th percentile body weight (United Nations University et al. 2004; WHO 2006b) as they have higher energy needs per kilogram of body weight than girls of the same age.

For model diets for three and nine month old infants and one year children, consumption amounts take into account the energy requirements of infants and the energy content of human milk, infant formula, follow-on formula or toddler milk. Model diets for three-month old infants assume food

consumption is exclusively human milk or infant formula. Model diets for 9-month old infants and one year old children assume that 50% and 35% of energy intake, respectively, is derived from human milk, follow-on formula or toddler milk, with the remaining energy derived from all other foods and beverages consumed (Hitchcock et al. 1986).

If required, the patterns of solid food consumption of a two-year-old child from the 2011-12 NNPAS, derived using *Harvest*, are scaled down in proportion to total energy intakes and used to determine the solid portion of the model diet for 9-month old infants and one year old children. Certain foods such as nuts (excluding peanut butter), coffee and alcohol are removed from the model diet, and other 'infant specific' foods are included e.g. infant cereal.

Because a model diet is only an estimate of what a typical diet might be and is based on a single value of consumption for each included food, the distribution of intakes of nutrients or dietary exposures to other food chemicals in the infant and young children population is not able to be determined with any certainty. As an alternative, the 90th percentile dietary exposure may be approximated using the internationally accepted formula as show in Equation 9 (WHO 1985).

90th percentile exposure = mean exposure x 2

Equation 9: Approximating 90th percentile exposure equation (WHO 1985)

5.2.1.3 Higher tier deterministic exposure assessments

In higher tier, single-point deterministic assessments, a single food chemical concentration is multiplied by a single food consumption amount for each food that contains the food chemical of interest, with a single dietary exposure value being derived. The dietary exposure estimate may then be divided by the mean population body weight (see section 4.3.1) to obtain an estimate of dietary exposure for comparison with the relevant HBGV (see Equation 10). Deterministic assessments are straightforward to conduct and the outputs are relatively simple to understand. However, they do not provide information on the likelihood of the estimated level of dietary exposure occurring, nor the range of dietary exposures within a population.

The single food chemical concentration data points used are generally means, but sometimes medians or high percentile values are used depending on the purpose of the dietary exposure assessment. For concentration data the single data point may also be a proposed maximum concentration, or a maximum level in the Code (FAO/WHO 2020a). The single food consumption data points used are generally derived from individual NNS consumption amounts, such as the mean, median or 90th percentile consumption of all survey respondents or of a particular sub-group (FAO/WHO 2020a).

$$\text{Dietary exposure} = \frac{\sum(\textbf{single}\ \text{food chemical concentration} \times \textbf{single}\ \text{food consumption})}{\textbf{mean}\ \text{population body weight (kg)}}$$

Equation 10: Deterministic dietary exposure assessment equation

When conducting a standard deterministic calculation for a chemical in many foods (as opposed to a single food), mean consumption amounts should be calculated from all survey participants, regardless of whether they ate these foods or not (an 'all respondents' basis). This allows the addition of exposures from a number of foods as all consumption amounts are expressed across the same group of people. Generally, adding exposures for 'eaters only' of one food to 'eaters only' of another should not be done, as the consumer groups will usually be non-identical (not everyone who eats bread will eat fish for example).

Specific, internationally agreed, deterministic techniques are used for assessment of dietary exposure to agvet chemical residues. These are outlined in section 6.4.

5.2.2 Semi-probabilistic dietary exposure assessments

The most common technique FSANZ uses in dietary exposure assessment, is to match individual food consumption data from a NNS with a single point chemical concentration per food or food group, to generate a distribution of individual dietary exposures. FSANZ terms this technique 'semi-probabilistic', and it is conducted using *Harvest* (see Equation 11). This technique may also be referred to in other references as 'refined deterministic' (FAO/WHO 2020).

$$\textbf{Dietary exposure} = \frac{\sum(\textbf{single}\ \text{food chemical concentration} \times \textbf{individual}\ \text{food consumption})}{\textbf{individual}\ \text{body weight (kg)}}$$

Equation 11: Semi-probabilistic dietary exposure assessment equation

In this method, dietary exposures for each individual are calculated using their individual food consumption records (FAO/WHO 2020a). The specified food chemical concentration is multiplied by the amount of food that an individual consumed in order to estimate exposure from each food. Once this is completed for all of the foods containing the food chemical, the total amount of the food chemical consumed from all foods are summed for each individual. Where results are expressed on a body weight basis, each individuals body weight is used to adjust the individual's dietary exposure (see section 4.3.1). When individual records of food consumption are used, information can be generated on the distribution of food chemical dietary exposures in the survey population. Measures of central tendency and percentile exposures for the population can then be derived from the individuals' ranked exposures and compared to the relevant HBGV in addition to data on mean, median or percentile exposures for all consumers only. This method is particularly useful if a chemical is present in a wide variety of foods.

If the chemical is restricted to a limited or less commonly consumed food range e.g. sports foods, a specific consumption survey may be more accurate than using NNS and mean concentration data for a risk assessment.

5.2.3 Probabilistic dietary exposure assessments

A probabilistic technique involves using distributions of both food consumption and food chemical concentration data to produce a distribution of estimated dietary exposures (FAO/WHO 2020a) (see Equation 12). Information on the mean and high percentile dietary exposure is generated as with the semi-probabilistic techniques outlined above, and these estimated values are generally comparable if they are drawing on the same underlying consumption and concentration data. The value of a probabilistic exposure assessment is that it can also be used to estimate the probability of a population exceeding a given HBGV (Crépet et al. 2021; Kennedy 2023) and to assess uncertainty in the data used in dietary exposure assessments (FAO/WHO 2020a; Kennedy 2023).

$$\textbf{Dietary exposure} = \frac{(\textbf{distribution}\ \text{food chemical concentration} \times \textbf{distribution}\ \text{food consumption})}{\text{individual body weight (kg)}}$$

Equation 12: Probabilistic dietary exposure assessment equation

Probabilistic dietary exposure assessments are conducted using computer modelling because of the very large number of calculation steps involved. Probabilistic modelling software programs randomly select a consumption amount from the consumption distribution and multiply it by a randomly selected concentration from the food chemical concentration distribution, and any other data sets that may be used. This process is done over and over again to generate a distribution of potential exposures (Kennedy 2023). The results can be divided by a randomly selected body weight or, preferably, the consumption amounts are divided by the consumers' body weight before being included in the consumption distribution.

There have been recent developments in, and use of, probabilistic modelling in the international arena with the WHO using this technique for acute dietary exposure assessments of pesticide residues (Crépet et al. 2021). There are a number of commercial probabilistic modelling software packages available including @Risk, the Monte Carlo Risk Assessment (MCRA) software, The Cumulative and Aggregate Risk Evaluation Systems Next Generation (CARES NG) (FAO/WHO 2020a), Crystal Ball and Analytica. Other agencies internationally have developed their own customised probabilistic computer programs specifically for estimating dietary exposure. Further information on the types and application of probabilistic modelling techniques can be found in *Chapter 6 of EHC 240* (FAO/WHO 2020a).

FSANZ has used probabilistic techniques and the @Risk program in modelling associated with the risk assessment of microbiological hazards (FSANZ 2011; FSANZ 2012), and the risk assessment of acute dietary exposure to hydrocyanic acid in packaged salty snacks (see Figure 9) (FSANZ 2008a). It is typically used as a last tier in dietary exposure assessments if required, and only if the data required are available.

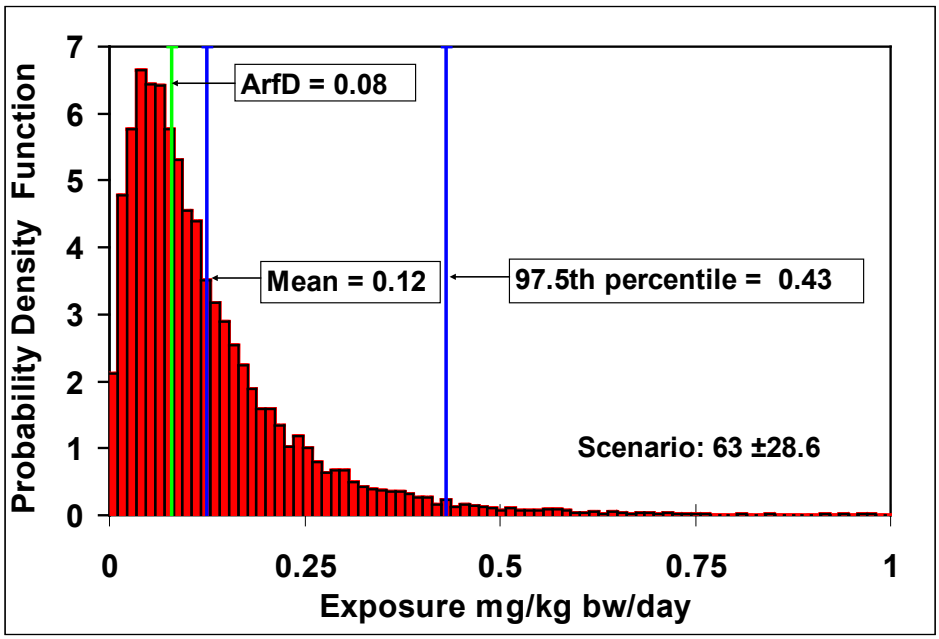

Figure 9: Distribution of exposure (mg/kg body weight/day) to hydrocyanic acid from cassava chips of Australian 2-4 year old children at a HCN concentration of 63±28.6 mg/kg (FSANZ 2008a)

5.2.4 Other types of dietary exposure assessments used by FSANZ

5.2.4.1 Cumulative dietary exposure assessments

A cumulative dietary exposure assessment is an assessment for two or more food chemicals that share a common mechanism of action, or synergistic or additive effects (FAO/WHO 2020a). The need to undertake a cumulative dietary exposure assessment will depend on the findings of the hazard characterisation step in the risk assessment process (FAO/WHO 2020a).

As outlined in *Chapter 6 of EHC 240*, several international guidance documents have been published for the risk assessment of mixtures or combinations of chemicals (FAO/WHO 2020a). In their Expert Consultation final report on *Risk Assessment of Combined Exposure to Multiple Chemicals* and *Chapter 6 of EHC 240*, the FAO/WHO recommend using a probabilistic approach

to dietary exposure assessment for estimating acute or chronic exposure to multiple chemicals (FAO/WHO 2019; FAO/WHO 2020a). Refined deterministic approaches may also be used for estimating chronic exposure (FAO/WHO 2019; FAO/WHO 2020a). FSANZ undertook a cumulative dietary exposure assessment for dioxins that took into account the TEF levels of 29 dioxin and dioxin-like congeners as part of the 26th ATDS using a semi-probabilistic approach (FSANZ 2021a).

5.2.4.2 Aggregate exposure estimates including sources other than the diet

Aggregate exposure assessments recognise that exposure to food chemicals may arise from the use of the same chemicals in non-food contexts. An aggregate exposure assessment is an estimate of exposure to a single chemical taking into account all its known sources and routes of exposure, such as from food, air, water, medicines, dietary supplements, and cosmetics. (FAO/WHO 2020a; Kennedy 2023).

At FSANZ, aggregate exposure assessments are not routinely conducted, other than to include information on possible oral exposure through the use of ingested medicines or dietary supplements. An example where aggregate exposure was considered is the assessment of total iron intakes from food, beverages and dietary supplements as part of *Application A1186 Soy leghemoglobin in meat analogue products* (FSANZ 2020a).

5.3 Population groups assessed

Ideally, dietary exposure assessments should cover the whole population, and where relevant, should also include 'at risk' or target population sub-groups. Wherever possible, FSANZ will account for these sub-groups in exposure assessments for both Australia and New Zealand. However, for some assessments there may be a lack of respondent numbers to enable the dietary exposure results to be derived or reported for different sub population groups, or to estimate or report usual intakes for specific age/sex groups and other specific populations (e.g. Socio-Economic Indexes for Areas (SEIFA) groups (ABS 2023)). Additionally, NNSs may not have been designed to identify specific sub-population groups or the data may not be available. Chapter 6 of this document identifies the sub-groups routinely reported in exposure assessments for different types of food chemicals.

A specific population sub-group may require a separate dietary exposure assessment due to a number of reasons:

- the sub-group may be identified as being 'at risk' during the toxicological or microbiological evaluation for a particular food chemical. These sub-groups may include infants, children, pregnant women, or older adults (FAO/WHO 2020a)
- there may be different HBGVs for different population groups e.g. NRV age and gender groups for nutrient assessments (NHMRC et al. 2006)
- certain population groups may consume particular foods in different ways and therefore may be at risk of higher levels of dietary exposure e.g. children (see section 5.3.2)
- the food chemical may be proposed to be added to foods consumed by one particular sub-group, e.g. infant formula products, sports foods, or foods for special medical purposes.

5.3.1 Pregnant /Lactating Women

NNSs undertaken in Australia and New Zealand to date have not been designed to capture specific information on food consumption during pregnancy and/or lactation by an appropriate number of respondents, therefore FSANZ is not able to model exposure for pregnant or lactating women. As an alternative, FSANZ will generally model exposure for women of child-bearing age, 16 - 44 years, as a proxy for pregnancy and/or lactation (FAO/WHO 2020a). A significant limitation to this approach is that it does not take into account changes women might make to their diet

during pregnancy and/or lactation, such as stopping or reducing consumption of alcohol and/or caffeinated beverages, introducing extrapolation uncertainty (Kettler et al. 2015). The effects of such changes are considered on a case by case basis where relevant. FSANZ may also consider data on dietary patterns during pregnancy and lactation from smaller surveys or studies, depending on factors such as study currency, methodological rigour, and sample representativeness when interpreting dietary exposure assessment findings derived from NNSs.

5.3.2 Infants and young Children

In general, dietary exposure results for the full survey population will be presented. However, where relevant, estimated dietary exposure of young children to the food chemical in question will be reported separately from that of the whole population. On a body weight basis, children have higher energy needs than adults because they are growing and developing as well as maintaining their bodies and therefore eat more food in relation to their body weight than adults do. This is particularly so for very young children. Children also consume more drinking water than adults on a body weight basis (WHO 2006a). Total food and water consumption is often high during adolescence as children grow very rapidly at this time (WHO 2006a) and exposure may be assessed separately where this is relevant.

Children may have unusual eating patterns, ranging from picky eating and food refusal, to disinhibited or binge eating (Taylor et al. 2015; Kjeldbjerg and Clausen 2023), that may be particularly relevant when assessing dietary exposure to some hazards. Very young children may eat a more limited range of foods than older children and adults, and therefore can be vulnerable to a hazard found in a particular food they eat (WHO 2006a; FAO/WHO 2020a).

The only times when children are unlikely to have higher dietary exposure per kilogram body weight than adults is when exposure occurs through a food or beverage not usually consumed by children, such as tea, coffee or alcoholic beverages.

No NNS data are available for New Zealand children less than 5 years of age, or for Australian children less than 2 years of age. Dietary exposure assessments produced for Australian children aged 2-4 years will be assumed to be applicable to New Zealand children of the same age, unless there is clear evidence to the contrary. Where relevant, model diets have been used by FSANZ in recent years to model food consumption and dietary exposure for infants and young children aged less than 2 years (see section 5.2.1.2.1). Other datasets for infants and toddlers as noted in sections 4.2.2.3.1 and 4.2.2.3.2, are now available providing data from individuals for FSANZ to use.

Dietary exposure assessments for children are undertaken routinely by FSANZ for nutrients and for agvet chemicals that have an ARfD established.

5.3.3 Ethnicity

FSANZ has not, to date, modelled dietary exposure according to country of birth or ethnicity, other than for Māori and Pacific peoples in New Zealand (FSANZ 1999). This is because ethnicity does not necessarily determine eating patterns, and also because there may be insufficient respondent numbers for some ethnic groups in NNS data to conduct robust assessments. In national surveys, the sample size for any population group which forms only 3-4% of the total population, such as Australian Aboriginal and Torres Strait Islanders (ABS 2022a) and people with certain health issues, is usually too small to provide a statistically viable sample. The NZ 2008 NNS and 2002 CNS over sampled Māori and Pacific people in order to obtain robust information on their dietary intakes and nutritional status (Ministry of Health 2003; University of Otago and Ministry of Health 2011).

Harvest has the capability to model for different eating patterns where appropriate. For example, a model could be run for 'high rice eaters' as a proxy for an 'Asian style' diet.

5.4 Duration of exposure

Duration of exposure is considered in FSANZ dietary exposure assessments in the context of whether or not a hazard presents a short term or long term risk. A short term risk is assessed using acute dietary exposure assessment techniques, while shorter-than-lifetime and chronic dietary exposure assessment techniques are used to assess longer term risks. Each of these assessments presents challenges in the appropriate use of food chemical and food consumption data. Although there are different general approaches that are followed for acute compared to shorter-than-lifetime and chronic assessments, the exact nature of the hazard being assessed determines the final dietary exposure assessment approach on a case-by-case basis.

5.4.1 Acute dietary exposure assessments

Acute dietary exposure assessments are conducted for food chemicals that have toxic or non-toxic effects from short term exposure (from one meal or over one day) (FAO/WHO 2020a). A Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals (FAO/WHO 1997) developed a methodology for performing short term (acute) dietary exposure assessments. This methodology, although developed and discussed in the context of agvet chemical residues, is considered applicable to all food chemicals where an ARfD has been established or where acute effects may occur following dietary exposure. FSANZ may also undertake acute or short term assessments for other chemicals, such as sugar alcohols, that may induce gastrointestinal effects after single large doses, but for which an ARfD is not established.

In estimating acute dietary exposure, the aim is to generate a 'worst case' assessment that takes into account the potential occurrence of someone who eats a large amount of a food happening to also select food that has a high concentration of the chemical in question. Therefore in a deterministic acute exposure assessment, a high consumption amount (typically the 97.5th percentile for consumers of the food) is multiplied by a high chemical concentration amount, where a distribution of chemical concentrations is known (FAO/WHO 2020a). If the number of consumers of a particular food is small, a lower percentile (e.g. 95th or 90th) of food consumption or a consumption value from a broader group of foods is used (FAO/WHO 2020a). In some circumstances a factor is also included to account for variability in the chemical concentration data set arising from lack of homogeneity in foods or due to small data sets being used (see Appendix 1). A highest residue from trial data may be used as the concentration for acute dietary exposure assessments for agvet chemicals, whereas a maximum permitted or use level may be used for a food additive.

FSANZ generally assesses acute exposure over a 24-hour period rather than for a single eating occasion, in line with international convention. This is because the food consumption data available were collected over a 24-hour period and any food eaten over one day could potentially be eaten on a single eating occasion. In a NNS with second day records, an individual's data can be pooled and treated as two separate days and not averaged over two days. Because exposure over a short time period is being assessed, the statistical adjustments that may be undertaken for chronic dietary exposure assessments (see sections 5.4.3 and 5.5) are not appropriate.

Although acute or short term dietary exposure assessments generally focus on exposure from a single food, exposure from a range of dietary sources can be taken into account if this is relevant. Whilst it may be unusual for someone to eat a very large amount of more than one food containing that food chemical at a high concentration level in a short period of time, this would be considered for each specific dietary exposure assessment to determine the likelihood and need for considering multiple foods in the one assessment.

FSANZ has used probabilistic modelling techniques to assess acute exposure to food chemicals (for example, see Figure 9) (FSANZ 2008a). This has the advantage over the deterministic assessment in predicting the likelihood of the 'worst case' actually happening and can take account of consumption of more than one food containing the food chemical at a time.

5.4.2 Shorter-than-lifetime dietary exposure assessments

Shorter-than-lifetime dietary exposure assessments are those conducted for food chemicals that have toxicological effects from exposure over a period of more than one day and less than a few years (FAO/WHO 2020a). These assessments may be particularly relevant for:

- food chemicals where the toxicological effect may be specific to a particular life stage (e.g. childhood, pregnancy)
- food chemicals where the NOAEL is greater in short term (e.g. 90 day) studies compared to longer term (e.g. 2 years) studies

or where:

- foods are habitually consumed at a high level over a shorter period of time such as:
    - seasonal foods e.g. summer fruit
    - foods consumed at a high level during developmental life stages e.g. childhood or pregnancy
    - foods consumed at a high level to meet medical requirements e.g. foods for special medical purposes (Arcella et al. 2019).

In a chronic dietary exposure assessment (where the toxicological effect is the result of lifetime exposure), it can be assumed that dietary exposure to a food chemical will approximate to mean adult dietary exposure, as the majority of a lifetime is lived in the adult phase. However, in the instances above, exposure estimates based on lifetime average consumption may underestimate shorter than lifetime risk (Boobis et al. 2017; Arcella et al. 2019).

FSANZ routinely reports estimated high consumer exposure in addition to mean consumer exposure (including for vulnerable sub-populations if identified during the hazard assessment) to ensure that shorter-than-lifetime risk is not underestimated. This approach is consistent with current international best practice (FAO/WHO 2020a). JECFA and JMPR are conducting further work in this area.

5.4.3 Chronic dietary exposure assessments

Chronic dietary exposure assessments are conducted for food chemicals that have toxicological (or nutritive) effects from exposure over a long period of time (FAO/WHO 2020a). Because exposure over a long time period is being assessed, it is not usually appropriate to select extremes of food chemical concentration data. Mean or median concentration data are most often used as, over a lifetime, people are most likely to consume an average concentration of a chemical in a food rather than continually be exposed to high levels of a chemical (FAO/WHO 2020a). There may, however, be assessments involving a subset of a population who have unusual eating patterns and who may select foods with persistent high chemical levels. For example, recreational fishers who regularly eat fish caught in a single area may have long term high exposures to chemicals present in waters in that area.

For chronic dietary exposure assessment, it would be beneficial for long term food consumption data to be used. However, collecting food consumption data over a long period of time is expensive and not conducted often, particularly at a national level. FSANZ uses 24-hour dietary

survey data to conduct chronic dietary exposure assessments. Therefore considerable care must be taken in using these data to represent long term food consumption patterns (see section 5.5).

5.5 Using 24-hour recall data to predict long term consumption, intake and exposure

Most of the NNSs used by FSANZ collected a single 24-hour recall for all respondents and a second 24-hour recall for some respondents, conducted on a non-consecutive day (see section 4.2.2). Using one 24-hour food consumption record may capture an unusual eating occasion for an individual that does not describe how they normally eat. This could potentially over- or under-estimate their typical food consumption. It could also exaggerate the reported extremes of food consumption across the survey group – on the day of the survey they may have eaten much more or much less of a food than their usual eating pattern. These are all sources of random error inherent in the 24-hour recall methodology (Bailey et al. 2019).

For consumers, mean daily food consumption amounts estimated from survey data may decline as the length of a survey increases, depending on the type of food consumed. For frequently consumed foods, the mean amount of food consumed per day, calculated from 1, 3, 5, 7, 10 or 14 day data, may not change significantly (Lambe et al. 2000); for example, consumers continue to eat a similar amount of bread every day. However, the daily mean consumption of occasionally consumed foods[8] may decrease if more than one day of data are considered. This is due to:

- the increase in the proportion of consumers of the food as the number of days increases
- the increase in non-consuming days among consumers (Lambe et al. 2000).

5.5.1 Estimating long term consumption and exposure from one day of food consumption data

The distribution of food consumption amounts for a survey of one 24-hour duration is much broader than that of an average calculated from two days (FAO/WHO 2020a) (see Figure 10). Therefore, the number of days of food consumption data affects the predicted high food consumption amount, which in turn affects estimated high percentile or 'high consumer' dietary exposure, particularly for food chemicals in occasionally consumed foods[8]. Where relevant, FSANZ reports dietary exposure for high consumers when assessing dietary exposure to food chemicals, as well as population average exposure.

High consumers can be those who consume:

- a lot of one food that contains a chemical of interest
- smaller amounts of a number of different foods that all contain the same chemical
- small amounts of a food which contains a high concentration of a chemical.

The data in Figure 10 are taken from the subset of 2011-12 NNPAS respondents who completed a second 24-hour recall and reported eating sausages (including in mixed dishes) on both days of the survey (n=59). The blue line shows the estimated consumption distribution for one day only (day one and day two pooled but considered as two separate eating days), whereas the orange line shows the distribution when estimated consumption amounts are averaged over days one and two (two-day average).

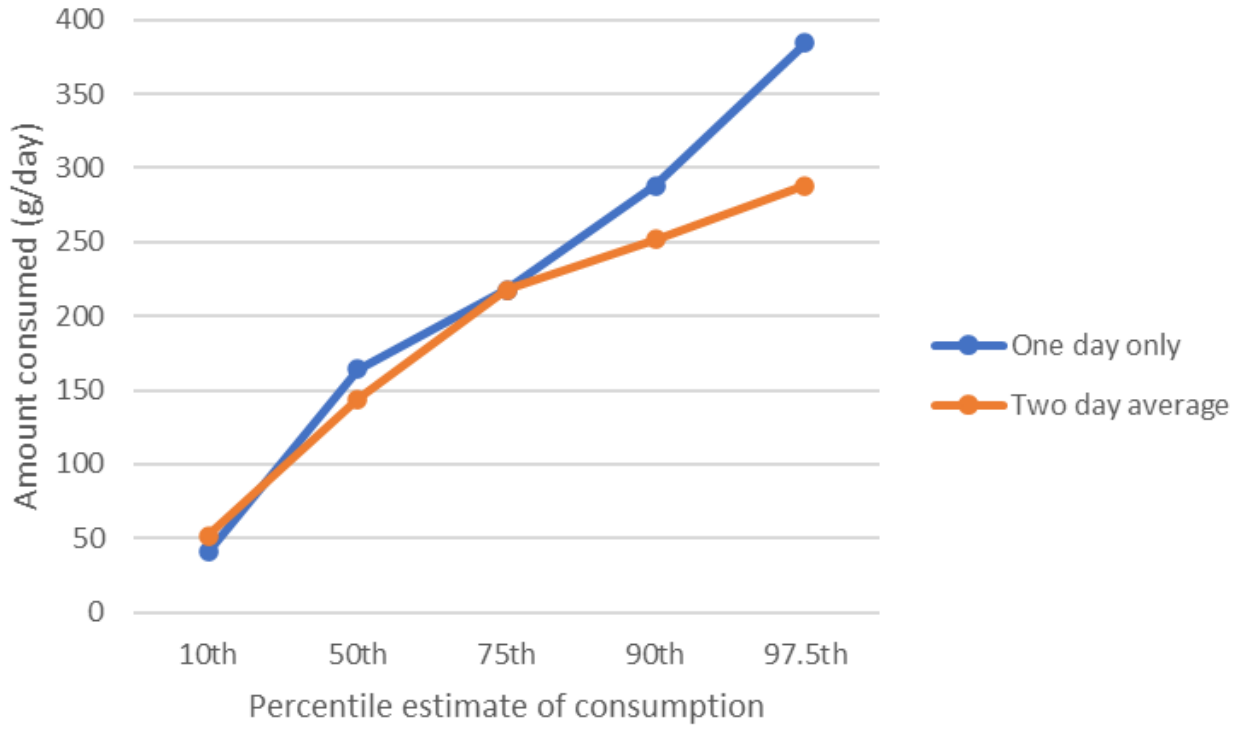

Figure 10: Estimated sausage consumption by all 2011-12 NNPAS respondents who consumed sausages on both days of the survey

Due to the the level of uncertainty about whether the upper end of the one day distribution range represents typical food consumption patterns for the population, and in keeping with international best practice (FAO/WHO 2020a), FSANZ has adopted a policy that a high consumer's chronic or long term dietary exposure to food chemicals (except nutrients) is best represented by the 90th percentile of exposure, where estimates of dietary exposure are based on food consumption data from one or two 24-hour recalls from a NNS.

Other percentiles are used to represent the high consumer for nutrient intake assessments and for acute exposure assessments of agvet chemical residues (see section 6.4.2) and contaminants. In some circumstances risk assessors and/or risk managers at FSANZ may choose to use other reporting cut-points, depending on the purpose of the risk assessment and the data sets available for use. In these cases, the reasons for doing so would be fully explained in the relevant FSANZ report, along with any accompanying evidence supporting the decision.

5.5.2 Estimating long term consumption, intake and exposure from two days of food consumption data

As outlined in section 4.2.2, the most recent Australian and New Zealand NNSs included a second non-consecutive 24-hour recall. To predict long term food consumption and food chemical exposure based on two days of consumption data, FSANZ uses either a two-day average methodology (for food chemicals except nutrients) or usual intake methodology (for nutrients).

5.5.2.1 Two-day average methodology

In the 2011-12 NNPAS, 64% of respondents (n=7,735) completed a second non-consecutive 24-hour recall (ABS 2013a). FSANZ often uses an average of the two days of food consumption for this group of respondents to provide an estimate of long term food consumption and food chemical exposure for chronic dietary exposure assessments. An alternative statistical adjustment may be

used to estimate usual food consumption amounts in some cases using the two days of data (see section 5.5.2.2).

For the 2011-12 NATSINPAS, the second survey day data collection did not include respondents living in remote areas (ABS 2013b). As the day two data are not representative of the whole survey population, data from day one only are used in FSANZ risk assessments.

Although a second 24-hour recall was completed for the 2002 NZCNS and 2008/09 NZANS (Ministry of Health 2003; University of Otago and Ministry of Health 2011), FSANZ does not estimate exposures using an average of two days of food consumption data for the New Zealand population as survey sample weights were not available for the second day data set (see section 4.3.2). In addition, there is a much smaller proportion of respondents with a second day of data. For these surveys long term consumption and exposure is estimated using one day of food consumption data, or the second day adjusted method for nutrients only (see section 5.5.2.2.1).

5.5.2.2 Usual intake methodology

The NRVs are defined as “the amount of nutrients required on an average daily basis for adequate physiological function and prevention of deficiency disease or chronic disease prevention” (NHMRC et al. 2006). Ideally, to assess chronic disease prevention, estimation of population nutrient intake would reflect usual dietary patterns over a long period of time. However available resources and respondent burden can limit the number of days of food consumption data collection (Bailey et al. 2019). Long term usual intake of nutrients can therefore be estimated using statistical adjustments where there is a second day of food consumption data for a representative subset of NNS respondents (Bailey et al. 2019). These usual nutrient intakes can then be compared to the NRVs (NHMRC et al. 2006), or for other food components to recommended levels for longer term intake (e.g. for caffeine). FSANZ may also report the estimated proportion of the population whose intakes are above or below the relevant HBGVs.

Figure 11 illustrates the effect of using this statistical adjustment on the predicted distribution of nutrient intakes and the potential this can have to alter interpretation of a population’s nutritional status, that is, the proportion of a population estimated to be above or below an NRV. Mean usual nutrient intakes will not be significantly different from single day mean intakes. However the 95th percentile usual intake will be lower than the 95th percentile single day intake and the 5th percentile usual intake will be higher than the 5th percentile single day intake.

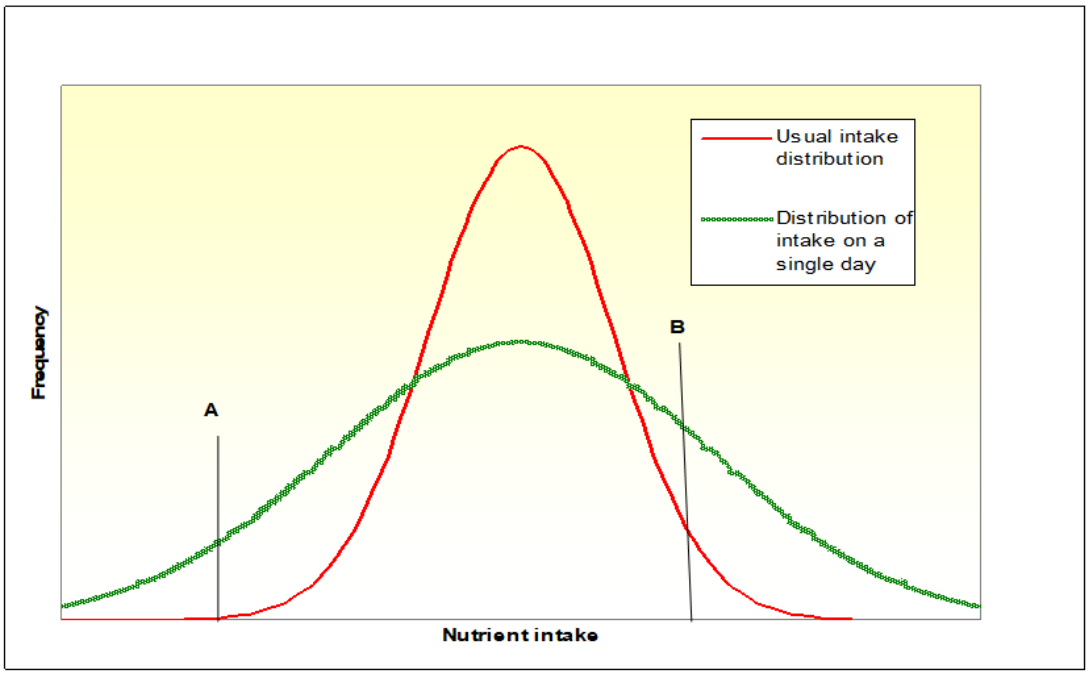

Figure 11: Comparison of one day and usual nutrient intake distributions. Points A and B represent NRVs for adequacy (A) and excess (B)

FSANZ uses two methods to estimate usual intake:

- within-person variance method (2nd day adjusted method in *Harvest*)
- National Cancer Institute (NCI) method.

These are explained in more detail below.

5.5.2.2.1 2nd day adjusted method for nutrient intakes

Usual intakes can be estimated in *Harvest* using what FSANZ refers to as the 2nd day adjusted method, namely the within-person variance method (Sempos et al. 1991). The within-person variance method is the technique that was used to produce the usual nutrient intake estimates for the 1995 Australian NNS (Rutishauser 2000), and both the 2002 NZCNS and 2008/09 NZANS using PC-Side software (Ministry of Health 2003; University of Otago and Ministry of Health 2011).

This adjustment process is appropriate to use for nutrients (except alcohol) as opposed to other types of food chemicals, because nutrients are widely dispersed in foods and therefore all respondents will have a nutrient intake on both days on which they were surveyed.

The 2nd day adjusted method works on the assumption that total variance in the outcomes of a survey reflect the sum of between person (the true difference between people in what they eat) and within person (the difference from day to day in one person) variance (Sempos et al. 1991). Therefore it estimates total variance and between person variance and adjusts each person's day 1 intake by a factor that is the ratio of these two standard deviations (noting that standard deviation is the square root of variance) (see Equation 13). This adjustment to day 1 intakes reduces the within-person variance (Sempos et al. 1991) and a distribution curve of 'usual' intakes for the population can be produced.

Harvest is able to calculate adjustments for specific age groups and specific nutrients and apply these adjustments to each individual's day 1 nutrient intake, to produce an estimate of usual nutrient intake. In essence, this technique takes the day 1 and day 2 intakes for each of those

individuals who were surveyed twice, and uses this to calculate the between-person standard deviation in nutrient intake. This value is then applied to all day 1 intakes as described above and in Equation 13 below.

Adjusted value = $x + (x_1 - x) * (S_b/S_{obs})$

Where: x is the group mean nutrient intake for the total weighted Day 1 sample
x_1 is an individual's day 1 nutrient intake
S_b is the between person standard deviation calculated using day 1 and day 2 intakes for those respondents surveyed twice
S_{obs} is the group standard deviation for the Day 1 sample

Equation 13: Calculating second day adjusted nutrient intakes (Sempos et al. 1991)

The estimation of usual intakes requires population nutrient intakes to be normally distributed. For some nutrients day one and day two intakes are very different and the distribution of intakes within the population is non-normal. In these cases, adjusted intakes are not able to be calculated using the above formula without additional manipulations being undertaken. Vitamin A, comprised of retinol and carotenes, is an example of this. Large differences in vitamin A intakes are found between day one and day two because this nutrient is concentrated in particular foods, such as liver (retinol) or orange vegetables (carotenes), and these foods are not usually eaten every day. Where intakes are not normally distributed, intakes can be log transformed by *Harvest* prior to the analysis of variance and then back transformed after the calculations are completed.

A minimum number of respondents in the second day are needed to generate a statistically valid adjustment of nutrient intakes. In the 1995 Australian NNS, 10% of respondents were asked to complete a second 24-hour recall (Rutishauser 2000). For the New Zealand NNS, the 25% (2008/09 NZANS) and 15% (2002 NZCNS) sub-samples for which two 24-hour recalls are available are considered sufficient to allow estimation of the within-person standard deviation for nutrients. FSANZ uses 'collapsed' age groups to ensure there are sufficient second day respondents in each adjustment group. However *Harvest* compares each individual's adjusted intake with the NRV for their actual age and sex (adjustment groups are broader than nutrient intake reporting groups).

For nutrient intake assessments, percent contributions of food groups to overall nutrient intake are reported based on day one intakes only. The methodology for estimating percent contributions based on adjusted intakes has not yet been investigated and developed by FSANZ.

FSANZ considers it reasonable to use the 95th percentile to report high percentile nutrient intake, and the 5th percentile for low nutrient intake, when an adjustment has been made for the second day of intake (e.g. usual intake using the NCI method or 2nd day adjusted methodologies). Different percentiles (i.e. 90th and 10th) are typically used for reporting long term nutrient intakes estimated using other methods such as the two day average. Care needs to be taken when comparing results from adjusted and unadjusted NNS data sets and from other studies.

5.5.2.2.2 2nd day adjustment of food consumption data and dietary exposures

It is not appropriate to use the same 2nd day statistical adjustment process for estimating food chemical dietary exposures or for food consumption amounts over time. Food consumption is highly variable from day to day and a 15% or 25% population subsample will generally be insufficient to generate enough consumers of a food to justify the use of the above statistical adjustment. In addition, food consumption across a population over a day is not normally distributed, and therefore exposure to food chemicals that are not present in all foods will also be non-normally distributed. The assumption of normality is necessary for the above adjustments to

be applied. The methodology used to estimate food consumption and dietary exposures to food chemicals in the long term is discussed in section 5.5.2.1.

5.5.2.2.3 National Cancer Institute (NCI) method for food and nutrient intake

Usual intakes of specific nutrients or food consumption can be estimated for population groups using the National Cancer Institute (NCI) Method (Tooze et al. 2006; National Cancer Institute 2023). The implementation of this method by FSANZ is consistent with the approach taken by the ABS and FSANZ in estimating usual nutrient intakes for the 2011-12 NNPAS (ABS and FSANZ 2015). Further information about this approach is available in the Australian Health Survey User Guide, 2011-13 (ABS 2013a). The only variation from the NNPAS implementation in estimating usual intakes is that at FSANZ the model is run in the statistical programming software R, rather than in SAS using the original code available from the NCI Method website (National Cancer Institute 2023). FSANZ translated the SAS code for the NCI Method into R (for version 3.0.3). At the time of this translation FSANZ undertook testing to validate the R code. The outputs from R were compared to those from SAS and the outputs were consistent between the two programs.

The NCI method assumes that "usual intake is equal to the probability of consumption on a given day times the average amount consumed on a consumption day" (National Cancer Institute 2023). In order to run the NCI method, the day 1 and day 2 nutrient intakes for each respondent from the NNS are calculated using *Harvest* and then used as the input for the NCI method.

The NCI method includes two different model types – the amount only model and the two part model. The amount only model is used to estimate usual intake for nutrients which are consumed by all or nearly all respondents. The two part model is used when more than 5% of respondents have a zero intake of the nutrient (see Equation 14 and Equation 15). The first part of the two part model estimates the probability of nutrient intake, and the second part of the two part model (also known as the amount only model) estimates the amount consumed on a consumption day (Tooze et al. 2006; National Cancer Institute 2023). The two part model is also more likely to be used for estimating usual food consumption as it is unlikely that all or nearly all respondents would have consumed the same food. There are two versions of the two part model, the correlated and uncorrelated versions. The correlated two part model is used when there is also a correlation between the probability of intake and the amount consumed (such as for caffeine). ABS used the uncorrelated version for alcohol in the 2011-12 NNPAS because the model would not converge (ABS 2013a).

Usual intake = probability x nutrient intake/food consumption amount

Where: probability of intake = 1

Equation 14: NCI amount only model for estimating usual intake of nutrients/foods that are consumed by all or nearly all of the population

Usual intake = probability x nutrient intake/food consumption amount on a consumption day

Where: probability <1

Equation 15: NCI two part model for estimating usual intake of nutrients/foods that are not likely to be consumed by all or nearly all of the population

"Covariates are data items or variables that describe characteristics of the individuals within a group, which are relevant to their nutrient intake" (ABS 2013a). The covariates used in the NCI method are sex, age, weekend versus weekday and sequence effect (which considers the potential reporting differences between day 1 and day 2 of the nutrition survey). The default of 100

simulations for each respondent is used in the Monte Carlo simulation component of the model. The model is run separately for three population groups: children up to 8 years, males 9 years and over and females 9 years and over. This ensures the model fitting is done more specifically using respondents with similar consumption patterns. Results are then extracted and reported by the NRV age/sex groups.

The NCI method is limited by needing at least two days of data, and where there are two days of the data, by the number of respondents with a second day of intake. Generally, at least 50 day 2 recalls in each age/gender group are required for the NCI method (ABS 2013a; Luo et al. 2022). Therefore the method is not suitable to assess usual intake for all surveys or for all specific sub-populations within surveys. The intake of specific nutrients from dietary supplements cannot be included in the calculations as a limitation of the NCI method is that it cannot estimate usual intakes from multimodal distributions (see section 6.6.4.1) (ABS 2013a).

5.6 Market weighted assessment

Applicants for new food additives or novel foods may provide information to FSANZ about the proportion of a food group that would be likely to contain the additive or novel food if it were approved for use. In a chronic dietary exposure assessment, this information can be useful to refine the assessment to more realistically estimate long term exposure to the chemical (FAO/WHO 2020a). FSANZ terms this approach a 'market weighted' assessment[18] and it provides information on the population average or high exposure to an additive assuming that consumers choose from a range of products, of potentially varying formulation, over their lifetime.

In a market weighted dietary exposure assessment FSANZ does not alter the NNS food consumption data (adding or deleting foods or altering amounts eaten) in *Harvest*. Therefore in order to integrate this market uptake information into the quantitative, semi-probabilistic assessments produced by *Harvest*, FSANZ alters the food chemical concentration assigned to a food group in proportion to the anticipated market uptake (FAO/WHO 2020a). For example, if a new food additive is likely to be used at a concentration of 2 mg/kg in 50% of low fat milk products, a concentration of 1 mg/kg will be assigned to 100% of low fat milk products. A second example is if 20% of intensely sweetened soft drinks contain 150 mg/kg of intense sweetener and 80% of intensely sweetened soft drinks contain 110 mg/kg of intense sweetener, a concentration of 118 mg/kg will be assigned to 100% of intensely sweetened soft drinks (see Equation 16). This will give an estimate of average longer term population-wide dietary exposure to a food chemical. However use of a weighted chemical concentration does markedly affect the extremes of exposure; it will underestimate exposure for those who deliberately consume a food containing the chemical and it will overestimate exposure for people who avoid the chemical.

50/100 x 2 mg/kg = 1 mg/kg in 100% of products

(20/100 x 150 mg/kg) + (80/100 x 110 mg/kg) = 118 mg/kg in 100% of products

Equation 16: Examples of altering food chemical concentration by market weighting

In the absence of information on market uptake, FSANZ will usually estimate dietary exposure on the assumption that 100% of a food category will contain the chemical. This is to ensure that dietary exposure is not underestimated and the risk characterisation errs on the side of caution.

In chronic dietary exposure assessments for agvet chemical residues, the proportion of a commodity actually treated with a pesticide could be taken into account, if known. However this information is not commonly available and therefore a market weighted assessment approach is not able to be used for this class of food chemical. In an acute dietary exposure assessment,

[18] Also called a market share adjustment (FAO/WHO 2020)

market uptake data can be used to describe the size of a population potentially exposed to the risk, it is not usually used in calculating estimates of dietary exposure because the exposure for high consumers based on a high concentration is of interest. Further information on and examples of the market share adjustment approach can be found in *Chapter 6 of EHC 240* (FAO/WHO 2020a).

5.7 Consumer behaviour assessment

A consumer behaviour assessment examines scenarios where consumers deliberately choose, or deliberately avoid, foods containing the food chemical. It can be also used to show dietary exposures where a consumer may be 'brand loyal' to specific products and therefore be regularly exposed to a given level of a chemical in that brand (FAO/WHO 2020a).

A consumer behaviour assessment is usually used where the chemical is deliberately added to specific foods (e.g. nutrient fortificants, food additives) and therefore it is assumed consumers are able to exercise choice regarding consumption based on label information. It is less relevant for environmental contaminants, natural toxicants and pesticide residues because it is not generally possible for consumers to know whether or not these chemicals are present in a food. However this style of assessment could be used for contaminants or natural toxicants where consumers may be:

- sourcing foods from a limited geographical location subject to a different contamination pattern
- choosing a type of food in which the levels of a contaminant or natural toxicant may be higher due to differences in production processes (e.g. food processing contaminant).

A consumer behaviour assessment can also be used to show how much of a frequently consumed food, commonly selected on brand, could be consumed on a daily basis before exceeding a HBGV. This was done for water based beverages in the risk assessment for *Application A1149 Addition of Steviol Glycosides in Fruit Drinks* by multiplying the MPL of steviol glycosides in water based beverages by the average body weight of respondents in the 2011-12 NNPAS (FSANZ 2019). The calculation showed that it would be unlikely, based on comparisons with the high consumption amounts of water based beverages reported from the most recent Australian and New Zealand NNSs, that brand loyal consumers would consume enough water based beverages over a lifetime to exceed the ADI (FSANZ 2019).

Figure 12 illustrates the effect on the estimated population intake of iodine of using a consumer behaviour assessment (assuming all consumers always choose, or never choose, iodised salt) compared to a market weighted assessment (consumers only using iodised salt in proportion to its market share).

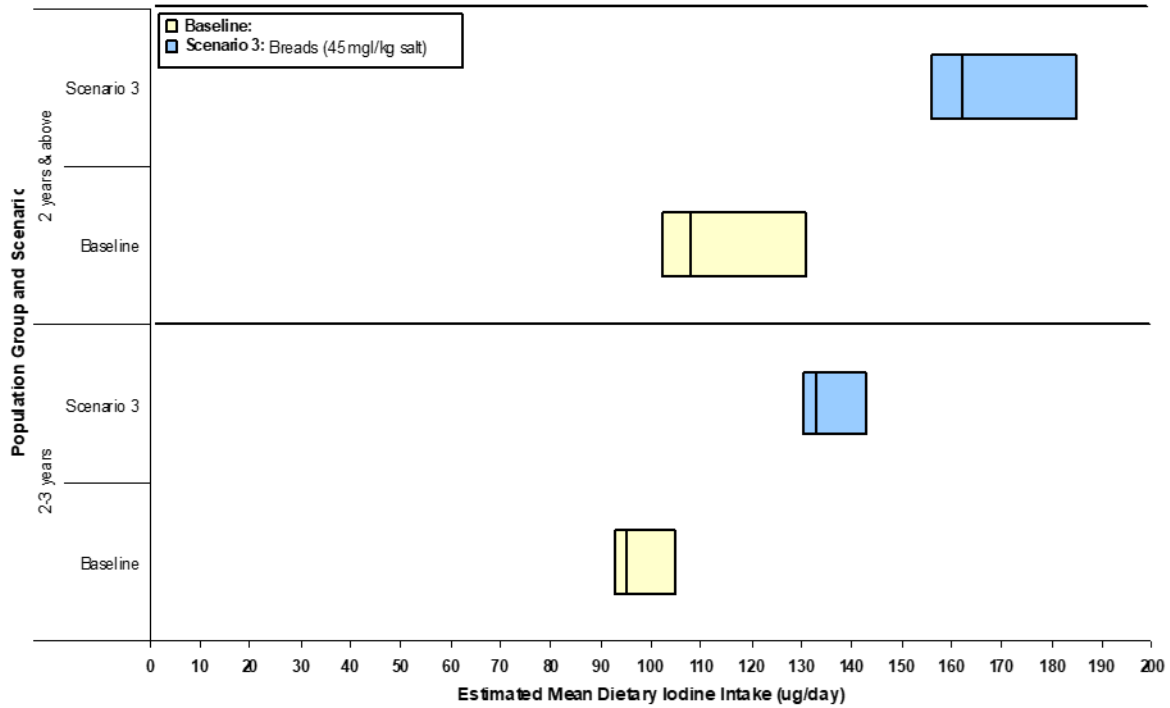

Figure 12: The effect of using a consumer behaviour assessment (represented by the lower and upper ends of the boxes) compared to a market weighted assessment (represented by the single black line within the boxes) on estimates of total iodine intake before (yellow boxes) and after (blue boxes) iodine fortification of salt used in breadmaking. The boxes show the range in iodine intake possible assuming consumers never choose iodised salt or always choose iodised salt, in cooking and at the table. Adapted from FSANZ (2008b)

5.8 Predictive or scenario models

FSANZ often has to estimate dietary exposure to food chemicals based on future predictions, generally in relation to a proposed change to the Code. This involves estimating current or baseline dietary exposures first, then undertaking a second estimate assuming certain foods or food groups will contain certain levels of food chemicals as proposed. These models are often referred to in FSANZ reports as ‘scenarios’. The exposure assessment may be an iterative process with risk managers, as results from the first set of scenario models may indicate the regulatory options to be considered may need to change with more scenarios modelled subsequently. Where scenario modelling is undertaken, the parameters and methods used to conduct the dietary exposure estimate are outlined in relevant reports.

The scenarios that are modelled will relate to the nature of the Application or Proposal to change the Code. For example, if an increased Maximum Permitted Level (MPL) is sought for a food additive, FSANZ may apply one or more increased ‘scenario’ concentrations to the relevant food group to predict dietary exposure taking into account exposure from all other foods, and determine whether the requested change would result in a dietary exposure that would exceed the HBGV. This helps to establish where a higher MPL could be set and still protect public health and safety.

5.9 Uncertainty

Uncertainty can be defined as “all types of limitations in the knowledge available to assessors at the time an assessment is conduced and within the time and resources available for the assessment” (Benford et al. 2018 p. 3). Of fundamental importance is the understanding that, whatever the consumption data, concentration data or methodology used, dietary exposure

estimates are just that, estimates, and due to the limitations in available knowledge, can never capture exactly what is eaten, or what is present in foods, at any given time. Therefore dietary exposure estimates will always have associated uncertainty.

The sources of uncertainty in dietary exposure assessment can be grouped into three broad categories (WHO/IPCS 2008; Kettler et al. 2015):

- Scenario uncertainty – these are uncertainties associated with the appropriateness of the approach and scenarios used in the assessment, the population sub-groups chosen, the data selected and the relevant time frames considered.
- Parameter uncertainty – these are uncertainties related to the food consumption data, food chemical concentration and body weight data used in the dietary exposure assessment.
- Model uncertainty – these are the uncertainties inherent in and specific to, the different models used in dietary exposure at FSANZ. Generally as the sophistication of the model increases in a tiered approach, the level of uncertainty decreases, however this is also associated with increased resource requirements.

Examples of how FSANZ addresses each broad category include:

- Scenario uncertainty – hazard assessment and characterisation are core steps in FSANZ's approach to risk assessment (see section 2.2.1) and their outcomes help to define how the dietary exposure assessment is set up.
- Parameter uncertainty – FSANZ uses analytical or industry food chemical data when available, and reports upper and lower bound exposures where relevant. FSANZ uses the most recent food consumption data from NNSs, and obtains additional food consumption data for sub-populations not included in NNSs e.g. infants and toddlers (see sections 4.1.5 and 4.2.3). Other sets of data (e.g. apparent consumption) may also be obtained to assist in making assumptions or to use in characterisation of the risk (see section 4.2.4).
- Model uncertainty – FSANZ selects the most appropriate model to answer the regulatory or risk assessment question(s) in a tiered approach, and where uncertainty exists, the source and management of the uncertainty are reported (see section 5.2).

At present, FSANZ does not quantify the uncertainty associated with all dietary exposure assessments as there are insufficient data available to enable this to happen. Quantitative descriptions of uncertainty that may be included in some exposure estimates include use of the upper-, middle- and lower- bound estimates of dietary exposure (see section 4.1.1.5.2.2), as well as use of the 90th percentile to represent high consumers with one day of intake (see section 5.5.1).

For most exposure assessments, sources of uncertainty are identified in reports as limitations and assumptions and a qualitative assessment may be produced at times (see Table 5). This information is important for interpreting the dietary exposure assessment results and the outcomes of the risk characterisation.

In future assessments, FSANZ may be able to quantify, or partially quantify, uncertainty in exposure estimates, although this will not always be necessary, for example when uncertainty is small or where it is unlikely to make any difference to the conclusions of the assessment. Further information about how uncertainty is recognised and addressed at FSANZ can be found in *Risk Analysis in Food Regulation* (FSANZ 2013a). International guidance on sources and management of uncertainty in exposure assessment can be found in a joint *WHO and International Programme on Chemical Safety report* (WHO/IPCS 2008), in *Chapter 6 of EHC 240* (WHO 2006a), and in European Food Safety Authority (EFSA) publications (Benford et al. 2018; EFSA Scientific Committee et al. 2018).

Table 5: Example of a summary presentation of the qualitative evaluation of the impact of uncertainties for estimating dietary exposures to packaging materials (FSANZ 2016a)

Sources of uncertainty	Direction and magnitude*
Consumption data: theoretical maximum physiological levels are used	+++
Exposure scenario: % of foods that contain packaging that is source of exposure unknown (assumed 50% in screening)	++/--
Exposure model: foods may not be representative of the Australian market	++/--
Model inputs: use of maximum concentrations as inputs where there are detections	+++
Model inputs: use of half LOR concentrations as inputs where there are no detections	++
Model inputs: uncertainty over analytical methodology leads to high level of uncertainty about non-detects and high upper bound means	+++
Model inputs: no analytical data on some key food groups	--
Model inputs: approach assumes that a consumer is randomly selecting foodstuffs. However, brand loyalty challenges this assumption	--

*plus signs indicate a certainty that could cause a small (+) medium (++) or large (+++) overestimation of exposure, minus signs small (-) medium (--) or large (---) underestimation of exposure.

5.10 Assumptions

Assumptions are necessary in all FSANZ's dietary exposure assessments, as discussed in several sections of this document. The aim of the dietary exposure assessment is to make as realistic an estimate of dietary exposure as possible. However, where significant uncertainties in the data exist, conservative assumptions are generally used to ensure that the dietary exposure assessment does not underestimate exposure (FSANZ 2013a). Assumptions for nutrient intake assessments may be slightly different given that intakes should not be over- or under-estimated (see section 6.6).

Assumptions can be general in nature, or can relate specifically to concentration data, consumption data or consumer behaviour. Some general assumptions that FSANZ uses can include that data for Australia or New Zealand are the same for the other country where data gaps for one of the countries exist. Another may be that concentration data from one source (e.g. overseas) are representative of what might be found in the food supplies in Australia and New Zealand. As for limitations and uncertainties, all assumptions made for a dietary exposure assessment are noted in the assessment report.

5.11 Conventions on reporting

A large number of data points are typically produced as part of a dietary exposure assessment undertaken using *Harvest*. Only some of these results, those that are central to an issue under investigation, will be presented in an assessment report. Other results can be presented in attachments to the assessment report or may be available from FSANZ on request.

Selection of the results for presentation depends on the complexity of the assessment that has been conducted, the nature of the hazard and the regulatory or risk assessment questions that need to be addressed. In general:

- Separate results will be presented for Australia and New Zealand.

- Results for the full survey population will be presented. Other age groups, vulnerable groups or target groups may be presented if relevant.
- Exposure or intake results will be expressed on the same basis as the HBGV used. For nutrients, total intake per day (e.g. grams or milligrams) will be reported whereas for other food chemicals, exposure will generally be reported on a body weight basis (e.g. mg/kg bw, µg/kg bw).
- Results may be presented graphically and/or in tables, but will generally not be presented in both formats within the main body of a report. Detailed information is generally provided within attachments to a report.
- FSANZ usually reports means and high percentiles for food chemical dietary exposures apart from nutrient intakes where a low, mean and high percentile are reported. If dietary exposures are not normally distributed, median exposure may also be reported depending on the assessment.
- When using food consumption data for individuals to calculate dietary exposure estimates, it is important to clearly distinguish between estimates calculated based on 'all respondents' (that is, everyone who completed the survey regardless of whether or not they reported consuming any foods containing the chemical of interest) and estimates based on 'consumers only' (that is, only those individuals who reported consuming at least one food containing the chemical of interest). Estimates of dietary exposure that are based on all respondents include any zero-value data points, which would result in lower mean, median and percentile exposure estimates being calculated from that distribution of values compared with estimates based on the exposures distribution for consumers only. Where essentially the whole population is exposed to a chemical, as is the case for nutrients that are present across many foods, estimates of exposure would be similar or identical between the two approaches.
- The weighted number and proportion of consumers is reported for all surveys where sample weights are available (see section 4.3.2).
- Results will be rounded as per the guidelines in section 5.11.1 below.

5.11.1 Rounding of results

FSANZ applies the following principles when presenting rounded results in reports:

- Dietary exposure estimates will be rounded to reflect the degree of certainty associated with the underlying data. Data are usually not reported to more than two significant figures, with a change of unit (e.g. from 0.001 mg to 1.0 µg) preferred to the presentation of large numbers of decimal places.
- When reporting dietary exposure as a percentage of a HBGV, exposure less than 10% of the guidance value will be reported to the nearest whole number (e.g. 9%), between 10 and 100% of the guidance value will be reported to the nearest 5% (e.g. 43% is reported as 45%), and greater than 100% of the HBGV will be reported to the nearest 10% (e.g. 107% is reported as 110%).
- When reporting the weighted proportion of consumers to respondents, percentages are rounded to one decimal place. A weighted proportion less than 1% is reported as <1%.
- When reporting the MOE, if the MOE is between 0 and 1000, the MOE is rounded to 1 significant figure e.g. 600. If the MOE is greater than 1000, the MOE is rounded to two significant figures e.g. 2700. This is in keeping with international best practice (FAO/WHO 2020b).
- When reporting food consumption data (g/day or g/kg bw/day), consumption amounts greater than or equal to 10 g will be rounded to the nearest whole gram, with amounts between 1 g and

10 g rounded to two significant figures, and amounts less than 1 g rounded to one significant figure.

- Percent contributions of food categories to total dietary exposure are reported rounded to the nearest whole number. A contribution less than 1% is reported as <1%.

5.12 Validation of dietary exposure assessments

FSANZ checks the findings of its dietary exposure assessments. Examples of checks that may be undertaken include:

- checking chemical concentration levels and mapping by a second staff member
- cross checking results with earlier, similar assessments
- cross checking results with international assessments (where available) or estimates published in the scientific literature
- manual calculation of some parameters, where feasible
- external review of assessment reports
- expert advice on methodological aspects.

5.13 Tools for dietary exposure assessment

When conducting dietary exposure assessments, FSANZ uses simple tools such as Microsoft Excel, as well as more sophisticated tools such as FSANZ's custom built computer program called *Harvest*. The tool selected for the dietary exposure assessment is based on a number of factors including the purpose of the assessment, the methodology that needs to be used, the type of data available, and the required outputs. *Harvest* contains all the national food consumption data sets outlined in sections 4.2.2.1 and 4.2.2.2, along with food chemical concentration data, classifications, recipes, and adjustment factors (see section 5.3). *Harvest* is programmed to calculate food consumption and dietary exposures (including comparisons to HBGVs) for the Australian and New Zealand populations, producing results which are used in FSANZ's risk assessment reports.

6 ASSESSING DIFFERENT FOOD CHEMICAL CLASSES

In this chapter, dietary exposure assessment techniques are outlined for the major categories of food chemicals that FSANZ assesses:

- food additives
- contaminants and natural toxicants
- agricultural and veterinary chemical residues
- novel foods
- nutrients
- nutritive substances
- processing aids.

Brief information is also provided on techniques that can be used to model dietary exposure to:

- packaging materials
- flavouring agents
- irradiation
- microorganisms
- genetically modified food
- secondary or inadvertent chemicals.

6.1 General approach

While there are general approaches for each class of chemical (see Table 6), the assessment of each individual chemical is conducted on a case by case basis. Table 7 sets out the usual reporting conventions for different classes of food chemicals. More specific details are explained further below in sections 6.2 to 6.14.

There are also many international guidelines for conducting dietary exposure assessments for different types of food chemicals. For example, there are guidelines for the estimation of food additive, pesticide residue, and contaminant dietary exposures that are published by the FAO and/or WHO in conjunction with the appropriate Codex committees (WHO 1997; Codex Alimentarius Commission 2014; FAO/WHO 2020a; Codex Alimentarius Commission 2022). FSANZ follows these international guidelines where applicable.

*Table 6: Information that could be used for conducting dietary exposure assessments for different classes of food chemicals**

Food chemical	Food additives and processing aids	Contaminants and natural toxicants	Agricultural & veterinary chemical residues	Novel foods	Nutrients
Consumption data	Raw and processed commodities	Raw and processed commodities	Raw commodities	Raw and processed commodities	Raw and processed commodities
Concentration data	Maximum permitted levels (MPL) from food standards Manufacturer use levels Analytical survey data Proposed use levels Food labels Branded food databases	Maximum levels (ML) from food standards Proposed MLs Analytical survey data (e.g. surveillance and TDS data) Scientific literature	Maximum residue limits (MRL) from food standards Analytical survey data (e.g. trial data, TDS data)	Maximum permitted levels (MPL) from food standards Manufacturer use levels Analytical survey data Proposed levels of use Food labels	Food composition data Maximum permitted amounts or claimable levels from food standards Analytical survey data Proposed nutrient fortification levels Food labels Branded food databases
HBGVs (Reference standard chosen depends on the nature of the assessment)	Acceptable daily intake (ADI) No adverse effect level (NOAEL) if no ADI Acute reference dose (ARfD) if set	Provisional tolerable daily (PTDI), weekly (PTWI) or monthly (PTMI) intake No adverse effect level (NOAEL) Benchmark dose (BMD) Acute reference dose (ARfD) if set	Acceptable daily intake (ADI) Microbiological ADI (mADI) Acute reference dose (ARfD) if set	Adverse effect level or as advised by FSANZ toxicologists Beneficial effect level as advised by FSANZ nutritionists Acceptable daily intake (ADI) Acute reference dose (ARfD) if set	Estimated average requirement (EAR) Upper level of intake (UL) Adequate intake (AI) Suggested dietary target (SDT) Acceptable macronutrient distribution range (AMDR)
Duration of exposure	Chronic Occasionally acute	Chronic Occasionally acute	Acute and chronic	Acute and chronic	Mainly chronic Occasionally acute

* Not all of these data sets are required before an exposure estimate can be conducted. Provided are examples of a range of data sources.

Table 7: Reporting conventions for FSANZ dietary exposure assessments for different classes of food chemicals

Food chemical	Food additives and processing aids	Contaminants and natural toxicants	Agricultural & veterinary chemical residues		Novel foods	Nutrients
			Chronic exposure	Acute exposure		
Population groups reported (general guide only; additional groups may be assessed depending on the specific risk assessment)	Australia: 2+ years New Zealand: 5-14 years 15+ years Infants 0-12 months and/or young children (depending on assessment)	Australia: 2+ years New Zealand: 5-14 years 15+ years Females 16-44 years Infants 0-12 months and/or young children (depending on assessment)	Australia only: 2+ years	Australia only: 2-6 years 2+ years Females 16-44 years	Australia: 2+ years New Zealand: 5-14 years 15+ years Infants 0-12 months and/or young children (depending on assessment)	NRV age and sex groups for the nutrient being assessed (NHMRC et al. 2006) Nutritive substances 3 months, 9 months or 12 months (if in infant formula products/FSFYC) Other population groups as necessary for the assessment
Adjustment for longer term consumption?	Two day average exposure may be reported for Australian population	Two day average exposure may be reported for Australian population	Two day average exposure may be reported for Australian population	N/A	Two day average exposure may be reported for Australian population	Usual intakes may be reported for Australian and New Zealand populations
Statistics reported	Mean and 90th percentile consumer exposure (chronic) Exposure on bw basis Exposure as % ADI/ARfD or as MOE % food group contribution to total exposure % population with dietary exposures > ADI/ARfD	Mean and 90th percentile consumer exposure (chronic) 97.5th percentile consumer exposure (acute) Exposure on bw basis & as % Tolerable Intake/ARfD % food group contribution to total exposure % population with dietary exposures > Tolerable Intake/ARfD	National estimated dietary intake (NEDI) (bw basis) NEDI reported as % ADI Mean and 90th percentile consumer exposure e.g. for ATDS % food group contribution to total exposure e.g. for ATDS	National estimated short term intake (NESTI) (bw basis) NESTI reported as % ARfD	Mean and 90th percentile consumer exposure (chronic) Basis of reporting (total, bw basis, % of HBGV) will depend on information available and assessment needs % food group contribution to total exposure	Mean, 5th, 50th and 95th percentile respondent intake when reporting usual intakes Mean, 10th, 50th and 90th percentile respondent intake when reporting intakes estimated using two day average % of respondents with nutrient intakes under the EAR/over the UL (where available) % food group contribution to total intake
Market weighted and/or consumer behaviour?	Likely	Unlikely	Unlikely	No	Likely	Likely

6.2 Food additives

The procedures used by FSANZ to assess the risks of food additive use are consistent with guidelines published by the Codex Alimentarius Commission (2014).

The general considerations for dietary exposure assessments for food additives are as follows:

- Food additives are specifically added to foods and therefore are usually in a restricted range of processed food and beverages. Dietary exposure assessments can therefore usually be restricted to these foods, except in cases where the food additive is also naturally occurring.
- Dietary exposure can be estimated using MPLs from the Code (Standard 1.3.1), and other sources of information. Manufacturers' use data or survey data are usually collected where no numeric MPL exists (e.g. where a Good Manufacturing Practice (GMP) permission is given), or where a more refined estimate of dietary exposure is needed.
- A dietary exposure assessment is not normally conducted to assess issues such as allergic or intolerance reactions.

The FAO/WHO guidelines (2014) outline two ways of expressing food additive intake at the International level:

- theoretical maximum daily intake (TMDI) based on MPLs (established in the Code or being sought by Applicants)
- estimated daily intake (EDI) based on actual use or measured levels.

Initially, TMDI and EDI calculations may be undertaken as a screening technique.

Screening techniques can be used by FSANZ to assess a new food additive. They are quick to undertake and can be very useful to illustrate in a simple manner the magnitude of potential exceedance of the HBGV and therefore provide early guidance to risk managers of the need to amend an Application or Proposal or to indicate the need for a refined dietary exposure assessment. Information on the screening techniques used by FSANZ is provided in section 5.2.1.1.

6.2.1 Food additive concentration data

For Applications requesting a new food additive permission or increased MPL, the dietary exposure assessment will use the proposed MPL or proposed maximum use level identified by the Applicant, together with MPLs for any existing uses of the additive. The proposed maximum permitted or use level will be assigned to a broad food group and all food groups with existing or proposed permissions for that additive will be included in the assessment. No further calculations are required if potential high exposures based on this conservative estimate are less than the ADI.

If initial estimates suggest dietary exposure will be above the ADI in one or more population groups, refinements to the additive concentrations, such as inclusion of market uptake estimates, or narrowing of the food group to more specific product types (e.g. apple juice instead of all types of fruit juice), can be undertaken. Actual use levels for foods with existing additive permissions either in the Code or available internationally could also be used.

In submitting dietary exposure data for Australia and New Zealand to JECFA or similar international group, FSANZ will use MPLs set out in the GSFA (FAO/WHO 2023c), matched

with Australian or New Zealand food consumption data, in addition to a separate assessment based on Australian and New Zealand concentration data.

If the food additive also occurs naturally in foods e.g. nitrites/nitrates, concentration data on naturally occurring levels may also be needed. This is usually required if it is considered that the amounts may be consequential to the outcomes of the assessment and therefore needs to be considered in the context of total dietary exposure. Analytical data from the Applicant or literature may be required.

6.2.2 Food consumption data

Food classes used in food standards for assigning food additive permissions and existing survey food mapping will be used to select the relevant consumed foods from each NNS. For example, if an additive is proposed for use in skim milk powder (class *1.5 Dried milk, milk powder, cream powder)*, all foods consumed that have been mapped to that food category will be assumed to contain the additive at the specified level. Assigning an additive level to all foods in this category will also ensure that the use of these foods as ingredients in other foods (e.g. milk prepared from powder) will automatically be accounted for because of the way in which *Harvest* has been set up.

Should the initial dietary exposure estimate indicate exposure above the HBGV, the specified concentration level would then be assigned to the specific food for which permission is sought (in this example, *Skim milk powder*) to derive a refined estimate.

Where relevant, exposure through non-food use of an additive (e.g. from medicines, supplements or cosmetics) may be considered. However an aggregate exposure assessment is not generally required for a food additive as exposure through non-dietary routes is often short term, whereas any hazards associated with food additives are generally of a long term nature.

Consumption of foods which are naturally occurring sources of a chemical that is also used as a food additive may be required if an assessment needs to include this dietary source.

6.2.3 Reporting of results

Table 7 identifies the usual conventions for reporting results of a chronic or long term dietary exposure assessment for food additives. Where a HBGV expressed on a bodyweight basis has been established, exposure will also be reported on a body weight basis. Where an additive is part of a group of additives for which there is a group HBGV, exposure assessments will take the potential additive intake from the whole group into account. Dietary exposure of males and females are generally not reported separately for food additives as this is rarely relevant in relation to the nature of the hazard.

For some additives, results may be presented for both a market weighted assessment and a consumer behaviour assessment e.g. in the risk assessment for *Application A1149 Addition of Steviol Glycosides in Food Drinks* (FSANZ 2019). Where an additive is not likely to be one specifically sought out by consumers, a consumer behaviour assessment is less relevant.

Under some circumstances, the percentage contribution to total exposure from different food groups will be reported, where this is helpful to understanding the dietary exposure assessment. By convention, FSANZ regards a major contributor to dietary exposure to be one that contributes 5% or more of total exposure; this aligns with Codex requirements (FAO/WHO 2023a). *Harvest* has the capability to identify individual consumers from each NNS whose calculated additive exposures exceed the HBGV. From their food consumption records, it may be possible to assess if there are specific foods that are likely to cause

excessive additive exposures. Contribution information may be useful to identify those foods that could be particular targets of risk management measures.

6.3 Contaminants and natural toxicants

The general considerations for dietary exposure assessments for contaminants and natural toxicants are as follows:

- Contaminants can occur naturally in the environment and therefore are often found in foods across the whole food supply.
- Some contaminants may be concentrated in certain food types, e.g. mercury in fish, acrylamide in heated carbohydrate-based foods.
- Natural toxicants always occur naturally in the environment, and are mostly associated with specific group of foods (e.g. mycotoxins, pyrrolizidine alkaloids).
- Dietary exposure is generally assessed using concentrations from survey data rather than Maximum levels (MLs).
- Contaminants and natural toxicants generally have the potential to cause chronic adverse effects, however on occasion, some contaminants and natural toxicants may present an acute hazard.

The potential range of food contaminants is very large and chemically diverse and includes both naturally occurring and synthetic chemicals. Contamination can occur under a variety of circumstances and levels of contamination can be difficult to predict. This necessitates the use of a range of approaches to estimating dietary exposure for contaminants. In general, the procedures used by FSANZ to assess the risk of food contamination are consistent with guidelines recommended by Codex (FAO/WHO 2020a; Codex Alimentarius Commission 2022).

Screening techniques can be used by FSANZ to assess contaminants and natural toxicants. They are quick to undertake and can be very useful to assess in a simple manner if there is a potential to exceed the HBGV based on worst case or conservative inputs and assumptions, and therefore provide early guidance to risk managers of the need for a refined dietary exposure assessment. Information on the screening techniques used by FSANZ is provided in section 5.2.1.1.

The risk associated with the majority of chemical contaminants and natural toxicants in food, at the levels at which they are normally present, is a long term one and therefore FSANZ will use chronic dietary exposure assessment techniques. Occasionally a contaminant or natural toxicant may present an acute risk, in which case acute exposure assessment techniques would be used (e.g. hydrogen cyanide (HCN)) (FSANZ 2008c). Acute exposure assessments for contaminants and natural toxicants may be conducted using either deterministic or probabilistic exposure assessment techniques.

One of the difficulties of estimating contaminant and natural toxicant dietary exposures is the need to combine data sets based on different premises, namely data on contaminant levels (generally based on commodities) and data on food consumption (generally based on individual foods as consumed). *Harvest* contains recipe information that can be used to disaggregate NNS consumption data for processed foods to the equivalent unprocessed commodities.

6.3.1 Contaminant and natural toxicant concentration data

The *Codex General Standard for Contaminants and Toxins in Food and Feed* notes that "it is desirable to have information about the contaminant concentrations of those foods or food groups that (together) are responsible for at least half and preferably 80% or more of the total dietary intake of the contaminant, both for consumers with average and high consumption patterns" (Codex Alimentarius Commission 2022 p. 5).

In the first instance, a dietary exposure assessment for a contaminant or natural toxicant could use the maximum level (ML) set out in the Code, if such levels are established. However MLs are only established for foods that are major contributors to dietary exposure or where they contain concentrations that require management when considering public health and safety. MLs therefore only exist for a small number of commodities which potentially contain the contaminant of interest, and therefore use of MLs alone will potentially underestimate dietary exposure to the contaminant or natural toxicant unless some allowance is made for minor contributors. Where MLs are set, they are generally set at the higher end of the usual range of contaminant concentrations i.e. the 95th percentile. For all these reasons, FSANZ does not usually use MLs when undertaking dietary exposure assessments for contaminants. Guideline levels, such as Generally Expected Levels (GELs) (Abbott et al. 2003), trigger points, or levels set by Codex, WHO or bodies such as the NHMRC (Australian Drinking Water Guidelines only (NHMRC and NRMMC 2011)) could be used in the dietary exposure assessments where relevant.

For newly-identified contaminants or natural toxicants, there may be no regulatory or guideline levels established that can be used in a dietary exposure assessment. Therefore other data sources such as survey data, are likely to be required.

Contaminant and natural toxicant concentration data are available from a variety of sources in Australia and New Zealand including total diet studies, government surveillance data, industry funded surveys, the Imported Food Inspection Scheme (IFIS) Australian Government Department of Agriculture, Fisheries and Forestry (2022), and research papers. Data on contaminants that are also nutrients (e.g. selenium, copper) are available from nutrient databases or food composition tables. International contaminant data are available from GEMS/Food (WHO 2023a) for a range of commodities. The amount of data available on contaminants and natural toxicants varies considerably and for most commodities the contaminant or natural toxicant data set is not extensive, particularly where a contaminant or natural toxicant is newly identified. Certain commodities that are known contributors of contaminants or natural toxicants are often targeted for analyses, for example fish, seafood and offal. FSANZ contributes contaminant and natural toxicant concentration data to GEMS/Food from its surveillance programs.

The options available to FSANZ for the treatment of ‘non-detected’ values in a dietary exposure assessment are outlined in section 4.1.1.5.4. The options typically used for contaminants and natural toxicants are outlined further here.. Depending on the nature of the contaminant or natural toxicant, FSANZ may assign a half LOQ to all non-detected results, or may report a range of dietary exposure between non detects being assigned a zero and being assigned a LOQ value. The approach used will be documented in the dietary exposure assessment report.

Compliance surveys or other targeted surveys may sometimes be used as a data source, depending on the circumstances of the assessment. If used, the limitations of these data will be documented.

6.3.2 Food consumption data

Harvest raw commodity grouping classifications will be used to select the relevant consumed foods from each NNS with recipes used to identify mixed foods containing the raw commodity as an ingredient.

Exposure to some contaminants or natural toxicants may arise through non-dietary routes. While generally this cannot be accounted for in the dietary exposure assessment, it will be noted in the assessment report where relevant.

6.3.3 Reporting of results

Table 7 sets out the usual conventions for reporting the results of a chronic or long term dietary exposure assessment for contaminants and natural toxicants. Where a contaminant is part of a group of contaminants for which there is a group HBGV, exposure assessments will take the potential contaminant intake from the whole group into account. For contaminants or natural toxicants without a HBGV, such as a genotoxic carcinogen, total exposure will be reported as well as the margin of exposure.

Dietary exposure for females of reproductive age is often reported separately as some contaminants may pose a particular risk to the developing foetus. Very young children are commonly assessed separately to pre-school age or older children because of the typically higher exposure of very young children to food chemicals, when expressed on a bodyweight basis. In addition, the adverse effects of the contaminant or natural toxicant may be more important for very young children.

Consumer behaviour assessments are generally not relevant to the dietary exposure assessment of contaminants or natural toxicants as consumers would not be expected to intentionally select or avoid foods containing a contaminant or natural toxicant. However consumer behaviour assessments may be presented if a sub-group of consumers regularly consume foods with higher concentrations due to geographic location, occupation, or production processes which are relevant to processing contaminants.

The percentage contribution to total exposure from different food groups will be reported as this allows identification of the foods where risk management actions should be focussed. By convention, FSANZ regards a major contributor to contaminant dietary exposure to be one that contributes 5% or more of exposure; this aligns with Codex requirements (FAO/WHO 2023a). *Harvest* has the capability to identify individual consumers from NNSs whose estimated contaminant or natural toxicant exposure exceeds the HBGV. From their food consumption records, it may be possible to assess if there are specific foods that are likely to cause these high exposures.

Under an acute exposure assessment for a contaminant or natural toxicant, 97.5th percentile consumer exposure is generally reported. If available, two days of consumption data are pooled (as individual eating days, not averaged across two days) before estimating the 97.5th consumer exposure (see section 5.4.1). Very young children are generally the focus of an acute exposure assessment for a contaminant or natural toxicant because of the typically higher exposure of very young children to food chemicals, when expressed on a bodyweight basis.

6.4 Agricultural and veterinary chemical residues

Dietary exposure assessments performed by FSANZ for agvet chemical residues are conducted in conjunction with the Australian Pesticides and Veterinary Medicines Authority (APVMA), under an established protocol. The APVMA registers and approves all agvet

chemical use in Australia and sets MRLs for these chemicals in agricultural produce, particularly domestic produce entering the food chain (FSANZ 2023m). Through FSANZ MRL Harmonisation Proposals (FSANZ 2023k), FSANZ also assesses dietary exposure to agvet chemical residues for imported foods, for which the APVMA does not have a role. Information about making a variation to a MRL for an agvet chemical is available at https://www.foodstandards.gov.au/food-standards-code/changing-the-code/limits.

The dietary exposure assessment techniques used by the APVMA and FSANZ are the same in both cases and align with international practices.

FSANZ assesses dietary exposure to agvet chemical residues for Australia only as Standard 1.4.2 in the Code only applies in Australia. New Zealand, under the Ministry for Primary Industries independently registers and approves Agricultural Compounds and Veterinary Medicines and establishes MRLs for food commodities in the MRL food notice (Ministry for Primary Industries 2023a).

The general considerations for dietary exposure assessments for agvet chemical residues are as follows:

- These chemicals are approved for use in food producing crops and/or animal commodities and therefore residues are usually in a restricted range of raw commodities and processed foods and beverages.
- They are assessed using chemical residue concentrations from established MRLs, trial data or analytical survey data, and Australian population food consumption data from NNSs.

The exposure assessment may be a chronic assessment only or may be both a chronic and acute assessment, depending on the toxicological properties of the chemical. Generally a deterministic approach is used to estimate dietary exposure to agvet chemical residues, except where the estimated exposure approaches or exceeds the HBGV.

6.4.1 Dietary exposure methodologies – chronic assessments

6.4.1.1 Agricultural and veterinary chemical residue concentration data

In many cases, trial data (e.g. supervised trial median residues (STMRs)) are provided by the APVMA for use in dietary exposure estimates associated with proposed new MRLs and are used as the basis for the exposure assessment when available. Residue trial data refer to the raw commodity as produced rather than the food as consumed, although these may sometimes be the same (e.g. for fruit). When STMRs are used in estimating dietary exposure, a more realistic estimate of potential dietary exposure over a lifetime is produced than if MRLs are used. Processing factors may be applied where relevant to take account of loss of, or concentration of, agvet chemicals from raw commodities as they are transported, stored, processed and prepared.

If STMR data are not available for the commodities that may contain a particular agvet chemical residue, existing or proposed MRLs will be used instead. All commodities with an existing or proposed MRL for a particular agvet chemical residue will be included in a chronic dietary exposure assessment, not just the commodity that is the subject of the proposal.

Whether a MRL or STMR is used in an assessment, it will generally be assumed that the concentration value for the chemical in question is applied to all commodities covered by that MRL/STMR, whereas in reality only a proportion of a crop or commodity may be treated with

that chemical. In some cases, FSANZ may take into account the estimated proportion of a crop that is treated, as a refinement to a dietary exposure assessment, if data are available.

At times FSANZ may also draw on other agvet chemical residue concentration data, depending on the needs of the assessment. Other sources of data include the National Residue Survey (NRS), which is conducted on a regular basis by the Australian Government Department of Agriculture, Fisheries and Forestry (2023). The NRS provides extensive data for agvet chemical residues in major raw commodities of importance for Australia in international trade, such as meat and wheat. However these data usually only present the number of commodities that pass or fail the relevant standards and therefore accurate concentration data are often not available.

The options available to FSANZ for the treatment on 'non-detected' values in a dietary exposure assessment are outlined in section 4.1.1.5.4. The options typically used for agvet chemicals are outlined further here. Where residue concentrations are reported as being below the LOQ, a value of zero is usually assigned to these foods because it is assumed that a not detected result means the chemical was not actually applied to that food. Where analytical survey data are used, mean chemical concentrations for each food are usually derived for use in the dietary exposure assessment (see 4.1.1.5.2.5).

The WHO collates member country concentration data on selected agricultural chemical and veterinary drug residues important to commodities in international trade (for example in the GEMS/Food database (WHO 2023a)). However such data are of limited use for dietary exposure assessments for individual countries because countries differ in permitted chemicals, MRLs, sampling and analytical procedures, laboratory quality controls, LOQs and calculation methods for samples with no detectable residues.

6.4.1.1.1 Use of Total Diet Study (TDS) data

TDS concentration data and dietary exposure estimates may be available for many agvet chemicals for which dietary exposure assessments are being conducted. TDS concentration data generally give a more accurate estimate of longer term dietary exposure because they are likely to incorporate a proportion of commodities that are not treated with a given chemical due to the sampling approach. In many cases, the TDS includes only information on the level of residues in foods as consumed, because foods are analysed as consumed rather than as raw commodities. Samples are also composited, resulting in an averaging effect on any residues present in individual food products. ATDSs provide an estimate of the agvet chemical residue dietary exposures for Australians in the survey period and can provide confirmation that established agricultural chemical controls for practical commercial conditions in Australia are resulting in safe dietary exposures. This is similarly the case for the New Zealand TDS. The ATDS dietary exposure estimates may also be used as an estimate of a background level of residue dietary exposure when predicting whether new or changed agvet chemical uses will have a public health impact or not. They can provide a more realistic estimate of dietary exposures for comparison with deterministic estimates of dietary exposures based on MRLs or trial data, in particular where the latter exceed HBGVs. These results may be presented together. Further information on ATDS data are on the FSANZ website (FSANZ 2023d) and in section 4.1.1.5.1 of this document.

6.4.1.1.2 Reduction/concentration factors

The levels of agvet chemical residues in foods are usually reported for commodities of trade, and adjustments are necessary to predict the content in the edible portion of the food or in mixed foods. Reduction (when residue levels decrease) or concentration (when residue levels increase) factors take into account changes in agricultural or veterinary chemical residue levels in commodities due to storage, processing, preparation and cooking, and are

normally applied to the residue concentration levels in the raw commodity in order to predict the residue level in the food as consumed. These are often referred to as ‘processing factors’ in the MRL DEA context (FAO/WHO 2020a).

For commodities which are processed and/or cooked, it is appropriate to apply mean reduction or concentration factors to the STMR level for the raw commodity, to produce an estimate of the residue level in the processed food (referred to as the STMR-P) (FAO/WHO 2009a). In some cases, residue data may be available for the edible portion of the commodity (for example, banana pulp) so that the STMR level can be estimated directly for the edible portion without applying reduction or concentration factors.

There are no standard reduction factors for use in exposure estimates, because different food preparation techniques will apply for each chemical, for each commodity and in each country. In Australia, for example, there are sufficient data on wheat to determine the concentration factor for wheat bran relative to wheat grain, and the reduction factors for wheat flour relative to wheat grain for selected agricultural chemicals.

For agvet chemical residues that are fat soluble, the differences in distribution of a specific residue in the meat/muscle or milk as a whole, and the fat portion, also need to be considered when determining appropriate reduction or concentration factors. No universal distribution ratio is possible because the relative amount of residue partitioned into the fat varies with each chemical. The assumption used by FSANZ is that there is a certain percentage of fat for each commodity, for example, 10% fat in meat/muscle and 4% fat in milk (as a worst case scenario) and 100% of the fat (e.g. lard), unless known otherwise. How this is applied in a dietary exposure assessment and selection of the consumption data to be used will depend on how the MRL was established. It may be that the MRL, whilst for a chemical that is fat soluble, is calculated to apply to the whole commodity (muscle including marbled and separable fat).

6.4.1.2 Food consumption data

For the purposes of the deterministic assessments conducted for agvet chemicals, FSANZ has developed data tables that report mean consumption for all respondents in the 2011-12 NNPAS for specific raw commodities for the whole population aged 2 years and above, to represent lifetime consumption of these commodities for chronic dietary exposure assessments.

Food consumption data for each commodity includes all uses of the raw commodity, from raw foods as well as processed foods and beverages, with the application of appropriate reduction or concentration factors and expression of foods in equivalent forms. For example, the consumption data for apples would include raw apples, cooked apples, apples in pies or pastries and apples in apple juice (converted to raw fruit equivalents).

Where a commodity was not consumed in the NNPAS but a MRL exists or is proposed, a default consumption figure (0.0001 g/kg bw/day) is used as an estimate of mean population consumption for the purposes of the chronic dietary exposure assessment conducted deterministically.

6.4.1.3 Dietary exposure assessment technique

There are two possible approaches to estimating chronic dietary exposures at a national level: theoretical maximum daily intake (TMDI), where dietary exposure estimates are based on residues at the MRL, or the national estimated daily intake (NEDI) where STMRs are used to represent residue levels in foods where available. Any one chronic dietary exposure calculation

may contain a combination of these but the NEDI is the approach most commonly used by FSANZ and the APVMA.

The NEDI can be defined as shown in Equation 17.

$$\textbf{NEDI} = \Sigma F_i \times \text{STMR-}P_i$$

Where: F_i is the average amount of the commodity reported as consumed by the whole population (i.e. all nutrition survey respondents)
$\text{STMR-}P_i$ is the supervised trial median residue level of the corresponding food commodity or MRL, incorporating processing/edible portion factors where appropriate

Equation 17: National estimated daily intake equation

Dietary exposures from all commodities with relevant uses of the chemical are summed to generate total exposure. This is done using a deterministic calculation and a single estimate of mean chronic dietary exposure for the whole population is the outcome. The consumption data are usually expressed on a body weight basis, to enable the estimated dietary exposure to be compared directly with the ADI.

When reliable data are available on the proportion of crop treated, a more refined estimate of dietary exposure to residues can be made by applying this factor for commodities that are sufficiently homogeneous in the food supply due to centralised processing and distribution (e.g. cereal grains or processed vegetables). Similarly, the proportion of crop that originates from domestic or imported sources can be used, where available and appropriate.

A chronic dietary exposure assessment for agvet chemical residues may also be conducted using *Harvest* but would generally only be done if exposure estimated using the NEDI were approaching or exceeding 100% of the ADI. As noted earlier, use of *Harvest* allows a more refined estimate of dietary exposure as it uses a semi-probabilistic methodology where a distribution of food consumption from all nutrition survey respondents is combined with a single concentration value for each commodity of relevance.

6.4.1.4 Chronic dietary exposures for extraneous chemicals

For some agricultural chemicals such as DDT, that are no longer permitted to be used in Australia, there may be some residues still found in the food supply due to environmental contamination of soil, crops and animal feed, or in imported food. These residues are usually considered as ‘contaminants’ and an extraneous residue limit (ERL) may be established. Chronic dietary exposure assessments for extraneous chemicals will be undertaken in a similar way to other agvet chemicals currently being used, to establish ERLs.

FSANZ toxicologists are responsible for setting or identifying the most appropriate HBGVs for chemicals with ERLs. Where there are no Australian HBGVs established, and these values have been established by JMPR, the JMPR values may be used for risk assessment purposes in Australia, following consultation and agreement between FSANZ and the APVMA.

6.4.1.5 Reporting of results

Table 7 identifies the usual conventions for reporting results of a chronic or long term dietary exposure assessment for agvet chemical residues. Dietary exposure of males and females are generally not reported separately for agvet chemical residues as this is rarely relevant in relation to the nature of the hazard.

The percentage contribution to total exposure from different commodities can be reported, where this is helpful to understanding the dietary exposure assessment. By convention, FSANZ regards a major contributor to dietary exposure to be one that contributes 5% or more of exposure; this aligns with Codex requirements (FAO/WHO 2023a). *Harvest* has the capability to identify individual consumers from each NNS whose calculated agvet exposures exceed the ADI. From their food consumption records, it may be possible to assess if there are specific foods that are likely to cause excessive dietary exposures. Contribution information may be useful by identifying those foods that could be particular targets of risk management measures.

6.4.2 Dietary exposure methodologies - acute assessments

An estimate of acute dietary exposure is required for each food or commodity for which an MRL is proposed for those agvet chemicals where an ARfD has been established. The general principles applying to acute dietary exposure assessments have been previously outlined (section 5.4.1). FSANZ uses deterministic modelling techniques to estimate acute dietary exposure to agvet chemicals.

All acute dietary exposure assessments are typically conducted on a single commodity basis, based on the assumption that high consumers of one commodity are not going to be high consumers of another commodity containing residues of the same chemical on any one day or in any one meal (FAO/WHO 2020a). Additionally, it is also unlikely that the same chemical is present on two or more commodities consumed at the same time. The national estimated short term intake (NESTI) is used to estimate acute dietary exposure according to the methodology described by the WHO (1997; 2001). There are four different NESTI equations for calculating dietary exposure depending on the commodity being assessed (FAO/WHO 2020a).

6.4.2.1 Food chemical concentration data

By international convention, the highest residue (HR) found in residue trials is used to estimate a ‘worst case’ exposure (FAO/WHO 2020a). Where relevant, this figure may be adjusted for processing effects (HR-P) (FAO/WHO 2009a). Monitoring data may not be appropriate for use in acute assessments as only a small proportion of any food group will be included in an analytical survey and it is possible that the survey may miss collection of the highest concentration samples. HRs are relevant for three of the four NESTI equations, however the STMR (or STMR-P) is used for assessments for bulked or blended commodities where it unlikely that the HR would be the final concentration in the food.

6.4.2.2 Food consumption data

In contrast to the use of mean consumption amounts for the general population in estimation of chronic dietary exposure to agvet chemicals, the NESTI modelling approach for acute dietary exposure assessment requires ‘large portion’ consumption data. By convention, the large portion is the 97.5th percentile consumption amount from a population of consumers, estimated over one day, not per eating occasion (FAO/WHO 2020a).

For the purposes of the NESTI assessments, FSANZ has developed data tables that report the 97.5th percentile consumption for specific raw commodities for the whole population 2 years of age and above, children aged 2-6 years, and females aged 16-44 years. Consumption amounts for groups and sub-groups of raw commodities are also provided (e.g. citrus fruits (group), and ‘oranges, sweet, sour’ (sub-group), in addition to the individual commodities ‘oranges, sweet’ and ‘oranges, sour’). These consumption data are derived from the 2011-12 NNPAS.

In some instances, particularly when considering population sub-groups, there may be insufficient consumer numbers to allow the derivation of a robust 97.5th percentile consumption amount for the large portion (FSANZ uses less than 39). In these cases the large portion size can be replaced by the large portion size for a closely related commodity within the same sub-group with 39 or more consumers, or commodity sub-group or broader commodity group, or from that of both raw and processed forms of the commodity (for example, peach consumption could be used to represent nectarine consumption).

If available, two days of consumption data are pooled (as individual eating days, not averaged across two days) before estimating the 97.5th percentile consumption amount for consumers used to estimate dietary exposure (refer to section 5.4.1).

6.4.2.3 Calculation of the NESTI

The exact equation used to calculate the NESTI varies depending on the commodity, taking into account the homogeneity of the commodity and the size of a unit of the food. These two factors can influence the uniformity of a residue distribution across different units of the food (e.g. across individual grapes in a bunch of grapes, or between packets of flour produced from the same silo of wheat). The formulae for calculating the NESTI are shown in Appendix 1: Calculation of acute dietary exposure for agvet chemical residues.

Unit commodity weight data are required for some NESTI calculations to make allowances for lack of homogeneity in residue levels in some commodities. Median unit commodity weights may be derived by the APVMA from residue variability trials where individual commodity units were analysed separately, but not from trials using composite samples. A comprehensive summary of Australian unit weight data is provided in Bowles and Hamilton (2001). If it is not possible to derive median unit weights for a commodity, other reference documents may be used to determine the mean weight of a medium sized unit of that commodity. This may include food composition datasets with food measures information.

The NESTI is calculated separately for the population 2 years and above, for children aged 2-6 years and females 16-44 years if applicable.

6.4.2.4 Reporting of results

Table 7 identifies the usual conventions for reporting results of an acute or short term dietary exposure assessment for agvet chemical residues. Where a HBGV expressed on a bodyweight basis has been established, exposure will also be reported on a body weight basis. Dietary exposures for the general population and children are not presented by sex, however are presented separately for females 16-44 years if there is a HBGV established for this group.

Under an acute exposure assessment for an agvet chemical residue, 97.5th percentile consumer exposure is generally reported.

6.4.3 Dietary exposure methodologies – international assessments

When dietary exposure estimates are produced at the international level or for international expert meetings, the chronic dietary exposure for agvet chemical residues has traditionally been estimated by the International Estimated Dietary Intake (IEDI). The consumption data used for the IEDI calculation are the GEMS/Food cluster diets (Sy et al. 2013; WHO 2023a). At the 2023 JMPR, the meeting decided to transition to the GECDE-mean (FAO/WHO 2024b) for chronic dietary exposure assessments. The GECDE calculation uses summary data from individual records from national dietary surveys from the FAO/WHO Chronic

Individual Food Consumption – summary statistics (CIFOCOss) database (FAO/WHO 2018) (see section 5.2.1.1.4).

At present at the international level, dietary exposures to veterinary drug residues are estimated by JECFA using the GECDE for chronic dietary exposure assessments and the Global Estimate of Acute Dietary Exposure (GEADE) for acute dietary exposure assessments (FAO/WHO 2011; Arcella et al. 2019; FAO/WHO 2020a; FAO/WHO 2024a). Probabilistic exposure assessments have also been used by the WHO to estimate acute dietary exposure to pesticide residues (Crépet et al. 2021).

At the international level, prior to use of the GECDE and GEADE, assessment of dietary exposure to residues of veterinary drugs had used a model diet that represented the upper limit of the range of daily consumption for individual commodities (edible tissues and animal products such as meat (300 g as muscle), liver (100 g), kidney (50 g), tissue fat (50 g), egg (100 g), honey (20 g) and milk (1.5 L) (FAO/WHO 2009b). These consumption amounts were multiplied by the median residue concentration and by the ratio of the concentration of the metabolite of concern to the concentration of the veterinary drug from which this metabolite is derived. This was summed for all relevant tissues to produce an Estimated Daily Intake (EDI).

These internationally used methodologies are not typically used by FSANZ for dietary exposure assessments because food consumption data from individual dietary records are available and can be used in different ways for the assessments being undertaken, however these other methods are available to use for assessments as needed.

6.5 Novel foods

The general considerations for dietary exposure assessments for novel foods are as follows:

- Novel foods are specifically added to foods and therefore are usually in a restricted range of processed foods and beverages.
- However some may occur naturally at comparatively low levels, and therefore consideration needs to be given in the dietary exposure assessment to including foods other than those to which an Application relates.
- The assessment may consider market uptake data and predicted consumer behaviour.

Dietary exposure assessments for novel foods are conducted in a very similar way to those for food additives (FAO/WHO 2020a), however there is often no HBGV for novel foods. In this case, risk characterisation will proceed as for an additive for which there is no ADI and a relevant point of departure is available (see section 4.6.2). Evidence provided to support a function for the novel food may include information on the level of intake required to achieve a certain health function, in which case this may be used in place of a HBGV to assess whether a suitable intake can be achieved through the proposed food use.

Novel foods may be foods in their own right, or more often added to foods as ingredients, for example plant sterols may be added to specific foods such as milk and yoghurt. More recently, FSANZ has started to assess cell cultivated proteins as novel foods in the Australian and New Zealand food supply.

6.5.1 Novel food concentration data

Before the dietary exposure assessment commences, there is generally a data compilation step where baseline or background levels of the novel food (e.g. from existing permissions or naturally occurrences) are assigned to the food consumption data. Information on levels of

natural occurrence may be supplied in Applications or be found in the scientific literature. If no data on natural occurrence can be found, the absence of this in the exposure assessment is noted as a limitation of the assessment and the likely impact of this discussed in the risk characterisation.

Scenario modelling will also be conducted in *Harvest*, using the proposed use levels provided by the Applicant, in addition to the baseline exposure (where relevant).

If the novel food contains nutrients or other chemicals either naturally occurring or associated with processing, intakes or exposures to these may be assessed separately depending on the hazard and/or nutrition assessment.

6.5.2 Food consumption data

Depending on the substance and how it will be consumed, foods will generally be grouped according to food additive or raw commodity classifications. Information on likely consumer purchasing patterns can be particularly useful for predicting exposure to novel foods, as these products are often intended to be used by a segment of the market rather than the whole population.

Where a novel food is used as an ingredient in a new food, consumption of a similar type of food currently available may be used to estimate potential consumption.

If the novel food is a food in its own right, and whilst novel in Australia or New Zealand is more commonly consumed overseas, consumption data from international sources may be sourced to provide indicative or worst case consumption amounts. Or, if the food is totally new to the food supply, such as in the case of cell cultivated proteins, anticipated consumption amounts may be provided by Applicants or consumption of a similar traditional food may be used as a surrogate for the assessment. A range of possible consumption scenarios may be modelled to evaluate a range of potential exposure scenarios in these cases.

6.5.3 Reporting of results

Table 7 identifies the usual conventions for reporting results of a chronic or long term dietary exposure assessment for novel foods. Exposure estimates will generally be reported as for food additives. However the dietary exposure of the proposed target group for the novel food may be assessed and presented separately. For example, a novel food may be promoted for use by post-menopausal women, in which case a separate dietary exposure estimate would be reported for women aged 50 years and above.

A consumer behaviour assessment may be conducted for the target population group. For non-target population groups, a market weighted assessment is more relevant, to predict incidental exposure through occasional use of a freely-available product.

6.6 Nutrients

The dietary exposure assessment procedures for nutrients differ from those for other food chemicals, because for nutrients FSANZ must assess both adequacy and safety.

The general considerations for dietary exposure assessments for nutrients are as follows:

- Intake assessments take into consideration naturally occurring levels of nutrients in foods and intakes from fortified foods.

- Intake assessments consider both adequacy of intake and safety of intake at baseline and after fortification.
- Intakes from dietary supplements and other sources need to be considered in the assessments, to the extent possible.
- Additional dietary intake assessments may be conducted when an increase in one nutrient may result in an inadvertent proportional decrease in another nutrient, however this will only be considered if the decreasing nutrient has an EAR.

6.6.1 Nutrient concentration data

Generally, the distribution of nutrients in the food supply is more widespread than for other food chemicals as most nutrients are present in a wide range of foods.

For both Australia and New Zealand, the results of each NNS were accompanied by survey specific detailed databases that provided nutrient concentration data for every food consumed in the survey. These survey nutrient databases are included in *Harvest* and used to estimate 'baseline' or current nutrient intakes prior to any proposed changes. These data are generally derived from analytical survey data, and other data sources such as label information, imputation and recipe calculation, not from maximum permissions in the Code.

The Australian NNS database is called AUSNUT, with the most recent version released to support the 2011-13 AHS (FSANZ 2023b). AUSNUT 2011-13 includes information on 5,704 foods and 2,163 dietary supplements reported as consumed as part of the 2011-12 NNPAS and the 2012-13 NATSINPAS, and is available as a series of downloadable files on the FSANZ website (FSANZ 2023b).

The main source of nutrient data for the 2002 and 2008 New Zealand NNSs was the New Zealand Food Composition Database (Ministry of Health 2003; University of Otago and Ministry of Health 2011). The most current database, in addition to previous versions are available to download from the New Zealand Food Composition Data website (New Zealand Institute for Plant & Food Research Limited and Ministry of Health 2022).

At times FSANZ needs to generate concentration data for nutrient components that are not included in the survey food composition databases. These data may be taken from national food composition reference databases (e.g. The Australian Food Composition Database (AFCD, previously known as NUTTAB), commissioned analytical surveys (subject to time and funds), overseas food composition tables, published literature, or may be calculated or imputed using established techniques (e.g. see Greenfield and Southgate (2003)). The origin of these data and their associated limitations will be identified in dietary exposure assessment reports. This may also be the case where it is necessary to create a new baseline if fortification (mandatory or voluntary) has changed the nutrients in foods since the survey datasets were developed.

The options available to FSANZ for the treatment on 'non-detected' values is outlined in section 4.1.1.5.4. The options typically used for nutrients are outlined further here. The treatment of 'non-detected' values for nutrients measured in analytical surveys for the purpose of the dietary intake assessment varies depending on the nutrient and the magnitude of the LOQ in relation to typical concentrations of that nutrient. Half LOQ is usually used for nutrients as both essentiality and safety are assessed and the value assigned should not over or underestimate the nutrient content where possible. For example, for trace minerals, a non-detected result may be assigned a value of half the LOQ. Minerals are typically widely distributed in foods and the very low levels found in many foods compared to the LOQ may make an important contribution to intake that should be accounted for (see 4.1.1.5.4). However for some vitamins, a non-detected result may be

assigned a value of zero as LOQs are generally low in relation to typical concentrations and therefore assigning a zero value will have no significant effect on estimates of intake for these nutrients. In addition, it may also be assumed that some nutrients are not present in a food, for example, vitamin E in water-based beverages.

6.6.1.1 Limitations of nutrient concentration data

The limitations of analytical food concentration data and individual food consumption data available to FSANZ are outlined in sections 4.1.1.5.2 and 4.2.3.1. The specific limitations of nutrient concentration data are outlined further here.

The overall nutrient composition of the food supply is not static for several reasons, including:

- changes to agricultural and animal husbandry practices
- new product development and changes to product formulations and processing
- seasonal variations in nutrient composition of the same food/ingredient and/or seasonal changes in ingredients
- changes in the regulatory environment, for example mandatory fortification of particular foods to address a public health need or new permissions for voluntary fortification
- changes in import patterns for foods.

Reported nutrient values can also vary between data sources due to changes in analytical techniques or modes of expression. These factors will be considered when conducting nutrient intake assessments.

Nutrient intake assessments conducted by FSANZ do not take nutrient bioavailability into account. The intake assessment focuses on the amount of the nutrient that reaches the digestive tract, not that which is ultimately absorbed by the body. Other parts of the FSANZ risk assessment consider this aspect.

6.6.2 Scenario nutrient levels for fortification assessments

The Food Standards Code prohibits fortification unless specifically permitted. Several classes of general and special purpose foods have permitted fortification for various reasons (e.g. address nutrient inadequacy, provide nutritional equivalence). Addition is regulated by setting a maximum claimable amount and possibly an additional higher compositional amount to mitigate risk if warranted. The maximum claimable amounts are generally at 50% or less of the daily intake value/serving.

FSANZ generally conducts nutrient intake modelling in association with Applications and Proposals to allow the fortification, voluntary or mandatory, of foods with nutrients. Therefore existing nutrient concentration data present in survey nutrient databases will need to be replaced with scenario nutrient levels for the relevant foods. This will be identified in the dietary exposure assessment report. If FSANZ is investigating mandatory fortification, an iterative process may be followed to determine the nutrient concentration level that provides the greatest increase in nutrient intake, particularly for the target groups, without leading to excessive intakes in one or more population sub-groups, particularly where a UL is established.

6.6.3 Food consumption data

Nutrient concentration data are prepared (either in nutrition survey databases or specifically for the assessment) for each food reported as consumed by each individual in the NNSs.

Therefore the consumption data for each food as reported in the NNSs are used for the dietary intake assessment. Consumption is totalled over a day for each individual, not by eating occasion. Between NNS, information on food and nutrient intakes can be obtained from ACSF data, however there are limitations associated with the use of these data for dietary exposure assessment (see section 4.2.5.2).

6.6.4 Dietary exposure assessment approach

Dietary exposure assessment techniques such as the screening per capita data approach are generally not used in Australia or New Zealand for reasons outlined previously (see section 5.2.1.1). The inherent tendency to overestimate food consumption with this technique is particularly problematic for nutrients because of the need to consider adequacy as well as excess. In addition, the availability of population nutrient intake data published through NNSs means that a better data source is readily available even without the use of dietary exposure assessment applications such as *Harvest.*

FSANZ routinely uses data from food consumption surveys for individuals for dietary exposure assessments where a nutrient is widespread in the food supply. *Harvest* is used for this purpose but the specific modelling techniques are somewhat different to those previously described for other types of food chemicals, and are detailed below.

Model diets may be used for children under the age of 2 years (Australia) or 5 years (New Zealand) (see section 5.2.1.2.1). The model is likely to be more complex than that for other food chemicals because there will be a wide range of foods that naturally contain the specified nutrient, as well as those foods that are fortified or proposed to be fortified.

A nutrient intake assessment is a chronic exposure assessment because generally long term, but not lifetime, intakes of a nutrient are of interest as some NRVs are set for different life stages. Acute exposure assessments are rarely conducted for nutrients.

One of the major differences between a nutrient intake assessment and other dietary exposure assessments that FSANZ carries out using *Harvest* is the ability to make statistical adjustments to predicted long term nutrient intakes (usual intakes) because of the availability of two 24-hour recalls for a subset of survey respondents. This feature is described in section 5.5.2.2.

6.6.4.1 The contribution of dietary supplements to total nutrient intakes

Predicted nutrient intakes may not be accurate where the use of dietary supplements such as vitamin and mineral supplements is common and is not taken into account. (Bailey et al. 2019). The most recent Australian and New Zealand NNSs included quantification of dietary supplement consumption (Ministry of Health 2003; University of Otago and Ministry of Health 2011; ABS 2013b; ABS 2015b), enabling inclusion of nutrient intake from dietary supplements into total nutrient intake assessments. There are however issues to be considered when estimating the contribution of nutrients from dietary supplements to total population nutrient intakes.

- Consumption of nutrients from food and beverages is often positively (or right) skewed, with some consumers having high intakes. Including intakes from dietary supplements with intakes from food increases this skewness, which may not be overcome through data transformation (Bailey et al. 2019).
- When considering nutrient intakes from dietary supplements alone, intakes are not normally distributed, even among consumers. This is due to dietary supplements containing fixed amounts of a particular nutrient, and consumers taking a set number of dietary supplements per day e.g. 1 or 2 tablets. Both these together create ‘spikes’ or a

multimodal distribution, with an additional spike (at zero) created if including non-dietary supplement consumers in the distribution (Bailey et al. 2019).

- The consumption patterns of dietary supplements may be different to the consumption pattern of foods and beverages. Dietary supplements may not be consumed by some people, consumed daily by some people, or consumed only at certain times (e.g. in winter, or if feeling unwell) by others (Bailey et al. 2019).

The contribution of dietary supplements to total nutrient intake have been considered in FSANZ risk assessments e.g. folic acid (FSANZ 2007b) and iron (FSANZ 2020a). Generally mean dietary supplement intakes from the 2011-12 NNPAS (ABS 2015b), or proposed dietary supplements intakes, are added to usual nutrient intakes from food and beverages for a population or sub-population of interest. The scenario results are then compared to the relevant NRV. This method is conservative as it assumes that all respondents are consumers of dietary supplements, however it is useful for risk assessment purposes.

6.6.5 Reporting of results

Table 7 sets out the reporting conventions for dietary nutrient intake assessments. Consumer intake is not generally reported separately to respondent intake as almost every respondent will be a consumer of the nutrient in question because of the widespread distribution of nutrients in foods. However consumer intakes may be relevant in the scenario where only a single food is to be fortified with the nutrient in question, and would normally be reported as a consumer behaviour scenario.

Reporting of intakes is generally against the age and sex categories set out in the NRVs (NHMRC et al. 2006) where relevant. The most appropriate NRVs are those established for use with populations (e.g. EAR, UL, AI) and not those established for use with individuals (e.g. recommended dietary intake (RDI)) (FAO/WHO 2020a). Intakes for women aged 16 – 44 years may also be reported separately where it is important to have a guide to possible nutrient intakes among women of child bearing age, as separate sets of nutrient reference values are often established to reflect the increased nutrient needs of pregnancy. Because NRVs are not expressed on a body weight basis, the dietary intake estimates for nutrients are not expressed in this way.

The percentage contribution from different food groups may be reported if this provides useful information on the overall contribution of a fortified food to nutrient intake. In this case, percentage contributions will generally be presented as the fortified food compared to the other foods, rather than reporting all foods that contribute 5% or more to intake.

6.6.5.1 Comparison of nutrient intakes with NRVs

In general, FSANZ uses the EAR cut point method to estimate the prevalence of inadequate intakes in the population (ABS 2013a). The proportion of the population below the EAR can be used for this purpose if the distribution of nutrient requirements is symmetrical around the EAR and the variance of the intake distribution is greater than the variance of the requirement distribution (ABS 2013a).

A small percentage of the population (i.e. 3% or less) with intakes below the EAR may be a reflection of the inaccuracies inherent in population nutrient intake datasets (ABS 2013a). Therefore, if less than 3% of a population group has an intake below the EAR, FSANZ considers that the population group as a whole has an adequate intake of the relevant nutrient. When assessing population intakes, two or more sub-groups with greater than 3% of intakes below the EAR spread across a broad range of ages has been considered indicative of an inadequate population-wide intake of a nutrient. This criteria has been used by FSANZ to support the need for fortification of the food supply when assessing an Application or Proposal.

FSANZ uses the UL to assess excess nutrient intakes. The proportion above the UL for each population group is usually estimated (NHMRC et al. 2006). There is no pre-determined cut off for an acceptable proportion of a population to exceed the UL. FSANZ considers each assessment on a case-by-case basis by and takes into account the extent of exceedances, the affected population groups and the toxicological endpoint and data used to set the UL.

Other NRVs such as SDTs and AMDRs which relate to chronic disease risks (NHMRC et al. 2006) are also used where appropriate and relevant to the assessment. Tolerable intakes may also be used for chemicals that are recognised as contaminants and are also nutrients (e.g. copper) (see section 4.6.1).

NRVs are not available for all nutrients. In the absence of an established NRV, other sources for risk characterisation purposes may include the Australian Dietary Guidelines (NHMRC 2013), New Zealand eating and activity guidelines (Te Whatu Ora Health New Zealand 2023) and World Health Organization guidelines (e.g. for saturated and trans fatty acids (WHO 2023c)).

6.7 Nutritive substances

In Standard 1.1.2-12 of the Code (Australian Government 2023)[19], a substance is defined as a nutritive substance if it is added to the food to achieve a nutritional purpose; and is:

- "any substance identified in the Code as one that may be used as a nutritive substance; and
- a vitamin or mineral; and
- any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised to achieve a nutritional purpose when added to a food".

For the dietary intake assessment of nutritive substances that are not a vitamin or mineral, FSANZ will use the same principles and procedures that are used for food additive dietary exposure assessments outlined earlier (see section 6.2).

For the dietary intake assessment of nutritive substances that are a vitamin or mineral, FSANZ will use the same principles and procedures that are used for nutrient dietary exposure assessments outlined earlier (see section 6.6).

6.8 Processing aids

FSANZ undertakes dietary exposure assessments for processing aids as appropriate, including for enzyme processing aids. A key consideration of whether a dietary exposure assessment will be undertaken depends on whether the residues of the processing aid and/or it's preparation remains in the food after production. Processing aid assessments may be for residues of a decontaminant meat wash or extraction solvents for example. Other considerations are when there is a proposed or existing MPL for residues in the Code. FSANZ will use the same principles and procedures that are used for food additive dietary exposure assessments outlined earlier (see section 6.2). These procedures may include screening techniques (e.g. budget method) or a more refined technique as required (see section 5.2).

[19] Sourced from the Federal Register of Legislation at 15 January 2024. For the latest information on Australian Government law please go to https://www.legislation.gov.au.

6.8.1 Enzymes

Enzymes are generally used as processing aids and are either not present in the final food, or present as an inactivated enzyme which would be metabolised like any other protein. FSANZ conducts dietary exposure assessments for enzymes as both a toxicology and a dietary exposure assessment are required to conclude that an ADI of 'not specified' can be established. This is in the case where FSANZ is assessing the enzyme processing aid for the very first time by way of an Application seeking to approve its use and relevant toxicological data are available and a point of departure (see section 4.6.2) can be determined.

FSANZ follows the FAO/WHO guidelines for enzyme assessments, also used internationally by JECFA (FAO/WHO 2020c). These guidelines include the consideration of dietary exposure, and may specifically consider the type and class of enzyme processing aid.

Dietary exposure assessments are conducted on the total organic solids (TOS) in the final enzyme preparation, and on any other relevant metabolites or toxins if these are produced by the microbial source and identified in the food technology and hazard assessments. A budget method calculation is usually undertaken based on current and proposed uses in food to calculate a TMDI, and a MOE derived by comparing the TMDI to a NOAEL (see section 5.2.1.1.2) (FAO/WHO 2020c). Where relevant toxicological evidence from the specific or a similar enzyme processing aid indicates there is no safety concerns, it may be decided that a dietary exposure assessment is not required. Similarly for specific uses of enzyme processing aid where residues are not expected to occur in the final food (e.g. highly processed or refined foods such as oils, syrups or distilled alcohol), it may be decided that a dietary exposure assessment for these types of uses is not needed. FSANZ can undertake a more refined dietary exposure assessment should the first tier budget method results indicate a need to do so.

6.9 Packaging materials

Although considered a contaminant in food, when assessing dietary exposure to chemicals migrating from packaging materials FSANZ may use the same principles and procedures that are used for food additive dietary exposure assessments outlined earlier (see section 6.2). This is because the contamination generally occurs at the level of the packaged final food, rather than at the raw commodity level.

Two different deterministic approaches to the assessment of chemical substances migrating from packaging materials are used by the European Union and the USA (FAO/WHO 2020a). Both approaches rely on model diets rather than the 'traditional' approach to dietary exposure assessments.

The European Union approach establishes a maximum limit of migration. This is determined by assuming a person weighing 60 kg could eat every day up to 1 kg of foodstuffs in contact with a plastic article containing the substance under evaluation, at the maximum limit, without exceeding the relevant HBGV. It also assumes that the contact surface area of the plastic material is 600 cm^2, and includes factors that account for consumption amounts of different food types (FAO/WHO 2020a).

The US approach assumes that people eat 3 kg of packaged foods and beverages each day and uses factors that describe the proportion of these foods that are likely to be in contact with specific packaging materials, not only plastics. Migration levels are assigned depending on the type of food (e.g. acidic, oily, water-based) as the rate of migration of a material contaminant varies with the food matrix and type of chemical (FAO/WHO 2020a).

Further information on FSANZ's approach for the risk assessment for packaging materials are in the risk assessment report for *Proposal P1034 Chemical migration from packaging into food* (FSANZ 2017) and the 24th ATDS (FSANZ 2016a).

6.10 Flavouring agents

"Flavouring agents are composed of divergent groups of materials including:

- artificial substances unlikely to occur naturally in food
- natural materials not normally consumed as food, their derived products and the equivalent nature-identical flavourings
- herbs and spices, their derived products, and the equivalent nature-identical flavourings
- natural flavouring substances obtained from vegetable and animal products and normally consumed as food whether processed or not, and their synthetic equivalents" (FAO/WHO 2009c pp. 9-8 - 9-9).

As flavouring agents are generally consumed in low amounts (FAO/WHO 2009c) FSANZ does not usually conduct dietary exposure assessments for this type of food chemical. Methods used internationally to estimate the dietary exposure to flavourings include the poundage data screening technique (see section 5.2.1.1.1), maximum survey-derived intake (MSDI) and single-portion exposure technique (SPET) (FAO/WHO 2020a).

Similar to the Poundage data technique, the MSDI is a screening method adopted by JECFA for flavouring agents using annual production data adjusted for underreporting and estimated consumption (FAO/WHO 2020a). In conjunction with the MSDI JECFA also uses the SPET, a model diet approach to account for regular consumers of foods containing a specific flavouring agent by assuming daily consumption of a single standard portion of food containing the flavouring agent at mean or usual use levels (FAO/WHO 2020a).

Further information on the uses and limitations of the MSDI and SPET can be found in *Chapter 6 of EHC 240* (FAO/WHO 2020a). FSANZ could use such methodologies should dietary exposure assessments to flavouring agents need to be undertaken.

6.11 Irradiation

Low level ionising irradiation is permitted in the Code to be used as a phytosanitary treatment for insect pest control on fruit, vegetables, herbs (and herbal infusions) and spices (FSANZ 2021b; FSANZ 2023g).

When conducting a dietary intake assessment for nutrients affected by irradiation, FSANZ will use the same principles and procedures that are used for nutrient intake assessments outlined earlier (see section 6.6). FSANZ generally considers:

- the contribution of fruit, vegetables, herbs (and herbal infusions) and spices proposed to be irradiated to intakes of irradiation sensitive nutrients (e.g. vitamin C)
- the nutrient content post-irradiation compared to natural variation
- the proportion of commodities to be potentially treated with irradiation
- the proportion of the population with inadequate intakes of irradiation sensitive nutrients (e.g. vitamin C)
- the potential impact on other bioactive compounds in fruit and vegetables (FSANZ 2021b).

Further information on the approach to risk assessment for nutrients affected by irradiation can be found on the FSANZ website (FSANZ 2023g).

6.12 Microorganisms

Exposure assessments for microorganisms provide an estimate of the likelihood that an individual or population will be exposed to a microbe and what numbers of organisms are likely to be ingested over a given time period. This could be for a microbial hazard or microorganism with potential health benefits. Exposure assessments for microorganisms differ from exposure assessments for chemicals as microorganisms grow and die.

The exposure assessment for microorganisms present in food can be either qualitative or quantitative, deterministic or probabilistic. In conducting an exposure assessment, FSANZ considers:

- the data available, including:
    - microbiological factors
    - properties of the final food and/or food ingredient
    - extent of contamination or level of addition to food
    - patterns of consumption
    - consuming population and susceptible sub-populations
- the whole food processing chain from ingredients to consumption
- other potential sources of the microbe.

Further information about the exposure assessment of microorganisms in food can be found in *Microbiological risk assessment guidance for food* (FAO/WHO 2021b).

6.13 Genetically modified food

All genetically modified food intended for sale in Australia and New Zealand undergoes a safety assessment by FSANZ (FSANZ 2023j). This may include a dietary exposure assessment if the genetic modification changes the nutrient profile of the food, for example food derived from super high oleic safflower (FSANZ 2018). If conducted, the dietary exposure assessment may include:

- a comparison of the nutrient composition of the genetically modified food with that of the conventional foods in the diet
- an estimation of the change in nutrient intake assuming the genetically modified food replaces or is consumed in addition to conventional food in the diet; and comparison with relevant NRVs
- any consequential changes in other nutrients and their intake as a result of the impact of the genetic modification.

Further information about FSANZ's safety assessment of genetically modified food is on the FSANZ website (FSANZ 2023j).

6.14 Secondary or inadvertent chemicals

When conducting a dietary exposure assessment for one food chemical, it may also be necessary to conduct additional dietary exposure assessments for secondary or inadvertent chemicals that are associated with the primary chemical of interest and present in the final

food. This assessment may be quantitative or qualitative depending on the specific assessment and the data available. These secondary or inadvertent chemicals may include:

- additional chemicals present in the solution or preparation containing the primary chemical under review
- chemicals formed during food processing
- metabolites or breakdown products of the primary chemical, formed either during production or processing, or in the human body following consumption
- chemicals that may impact on nutrient digestion and absorption (if considered in other parts of the assessment report)
- chemicals transferred to the final food through packaging or transport.

Applying the principles detailed in the sections above, FSANZ may conduct additional dietary exposure/intake assessments if the secondary or inadvertent chemical(s) either:

- has an existing or proposed HBGV
- has a specification in the Code
- is a nutrient or impacts on nutrient content where that nutrient has an EAR or UL.

These however are general considerations, and FSANZ will assess the need for any additional dietary exposure assessment on a case-by case basis.

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Appendix 1: Calculation of acute dietary exposure for agvet chemical residues (NESTI)

Abbreviations used:

LP	large portion, 97.5th percentile food consumption for the population of interest (kg/person/day)
HR	highest concentration of residue in composite sample of edible portion found in supervised trials from which the MRLs and STMR values were derived (mg/kg)
HR-P	highest concentration of residue in the processed commodity (mg/kg), calculated by multiplying the HR in the raw commodity by the processing factor
v	variability factor
U	unit weight in edible portion (kg), the mean/median weight of an individual commodity
bw	body weight (kg), mean of the population of interest

The variability factor (v) is used to represent the range of variability in residues in the individual units within the composite samples that have been analysed. A variability factor of three is used as a default (FAO/WHO 2020a).

There are four equations used to calculate the NESTI (FAO/WHO 2020a). Different equations are used for different commodities and these are outlined below.

Case 1
For commodities that are basically “homogeneous” when consumed due to the fact that there are a large number of individual units in a meal-sized portion (e.g. peas), the variation in residue levels between individual units is not considered to be of concern. Residue data based on analysis of composite samples are considered to adequately reflect the residues in a meal-sized portion. The cut-off for consideration under Case 1 is a unit weight of less than 25 g. Case 1 should also be used for animal commodities other than milk (e.g. meats, offal, eggs) and also for grains, oil seeds and pulses when the estimate of the HR or HR-P was based on post-harvest use of the pesticide.

$$\text{NESTI} = \frac{\text{LP} \times (\text{HR or HR-P})}{\text{bw}}$$

Case 2
For commodities that have individual units which contain heterogeneous residue levels, the variation in residue levels between individual units needs to be taken into account.

Case 2a
This specific case is applied when the median weight of an individual unit (unit weight) is less than the large portion (but greater than 25 grams), i.e. a consumer eats more than one unit in a single sitting or a day (e.g. apple, orange). The first unit is considered to be “hot” (i.e. a single unit contains a higher residue concentration than the composite) and a variability factor is applied to reflect the residues that may be present in a single unit compared to a composite sample. The remainder of the large portion is considered to contain residues at the highest residue level indicated by composite sample data.

$$NESTI = \frac{[U \times (HR \text{ or } HR\text{-}P) \times v] + [(LP\text{-}U) \times (HR \text{ or } HR\text{-}P)]}{bw}$$

Case 2b

This specific case is applied when the median unit weight is larger than the large portion. A consumer would eat less than 1 unit in a single sitting or a day (e.g. cabbage, watermelon). The particular unit from which the large portion is eaten may be a "hot" unit. A variability factor is applied to the whole large portion to reflect the residues that may be present in a single unit compared to a composite sample.

$$NESTI = \frac{LP \times (HR \text{ or } HR\text{-}P) \times v}{bw}$$

Case 3

For commodities that are basically "homogeneous" when consumed due to the fact that they are centrally processed (e.g. cereals, milk), the use of a variability factor is not considered necessary. Due to the bulking and blending involved in the central processing, the best indicator of the residue level that would be present in a meal size portion is considered to be the median residue observed in trials. The median residue observed in composite samples is considered to adequately reflect the residues in a meal-sized portion.

$$NESTI = \frac{LP \times STMR\text{-}P}{bw}$$

Notes

- The NESTI calculation should make the best use of the available data. HR and HR-P values should be corrected to reflect residues in the edible portion, e.g. residues in banana pulp rather than whole banana including the peel.
- The HR-P residue level can only be used in acute dietary exposure estimates when the entire commodity is processed or the commodity is always consumed only as the edible portion, for example, a banana without skin.
- HR-P and STMR-P values can be obtained directly from residue trials where the residue is determined in the processed commodity or they can be derived by application of the relevant processing factor.
- The variability factor can be refined where there are sufficient chemical-specific data depicting the variability in residue levels between single units. Typically analysis of at least 100 units containing detectable residues would be required to derive a variability factor.
- The application of factors for the percentage of crop or animals treated is not directly valid for acute assessments. Where a commodity is centrally blended (e.g. cereals, milk) the percentage of crop or animals treated may be a relevant consideration in the overall risk assessment. Where the percentage treated is very low and the commodity is always subsequently blended, then the STMR-P obtained from residue trials (i.e. all produce treated) may overestimate the residue level.

Appendix 2: Abbreviations and acronyms

ABS	Australian Bureau of Statistics
ACSF	Apparent Consumption of Selected Foodstuffs
ADI	acceptable daily intake (for food additives and agricultural & veterinary chemical residues)
AFCD	Australian reference nutrient composition database
Agvet	Agriculture and veterinary
AHS	Australian Health Survey
AI	adequate intake (for nutrients)
AMDR	acceptable macronutrient distribution range (for nutrients)
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	acute reference dose
ATDS	Australian Total Diet Study
AUSNUT	nutrient composition database used with Australian national nutrition surveys
BMD	benchmark dose
bw	body weight
EAR	estimated average requirement (for nutrients)
EDI	estimated daily intake
EHC 240	Environmental Health Criteria 240
EFSA	European Food Safety Authority
ERL	extraneous residue level
FAO	Food and Agriculture Organization of the United Nations
FFQ	food frequency questionnaire
FSANZ	Food Standards Australia New Zealand
FSFYC	formulated supplementary food for young children
GEADE	global estimate of acute dietary exposure
GECDE	global estimate of chronic dietary exposure
GEL	generally expected level (for contaminants)
GEMS/Food	Global Environment Monitoring System-Food Contamination Monitoring and Assessment Programme
GMP	good manufacturing practice (relates to use of food additives)
GSFA	(The Codex) General Standard for Food Additives
Harvest	FSANZ's custom built computer application used to calculate dietary exposure to food chemicals
HBGV	health-based guidance value

HR	highest residue (for agricultural & veterinary chemical residues)
HR-P	highest residue – processing (for agricultural & veterinary chemical residues)
IEDI	international estimated dietary intake (for agvet chemical residues)
IESTI	international estimated short term intake (for agvet chemical residues)
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	limit of detection
LOQ	limit of quantification
LOR	limit of reporting
ML	maximum level (for contaminants)
MOE	margin of exposure
MPI	New Zealand Ministry for Primary Industries
MPL	maximum permitted level (for food additives and processing aids)
MRL	maximum residue limit (for agvet chemical residues)
MSDI	maximum survey-derived intake
NATSINPAS	National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey
NCI	National Cancer Institute
NEDI	national estimated dietary intake (for agvet chemical residues)
NESTI	national estimated short term intake (for agvet chemical residues)
NHMRC	National Health and Medical Research Council
NNPAS	National Nutrition and Physical Activity Survey
NNS	National Nutrition Survey
NNSs	National Nutrition Surveys
NOAEL	no-observed-adverse-effect level
NRS	National Residue Survey
NRV	nutrient reference value
NZANS	New Zealand Adult Nutrition Survey
NZCNS	New Zealand Children’s National Nutrition Survey
PTDI	provisional tolerable daily intake (for contaminants)
PTMI	provisional tolerable monthly intake (for contaminants)
PTWI	provisional tolerable weekly intake (for contaminants)
RDI	recommended dietary intake (for nutrients)
SDT	suggested dietary target (for nutrients)
SEIFA	Socio-Economic Indexes for Areas

SPET	single-portion exposure technique
STMR	supervised trial median residues (for agvet chemical residues)
STMR-P	supervised trail median residues – processed (for agvet chemical residues)
TDS	total diet studies
TEF	toxic equivalency factor
TMDI	theoretical maximum daily intake
TOS	total organic solids
UL	upper level of intake (for nutrients)
WHO	World Health Organization

Appendix 3: Glossary

Defined below are a number of different terms used specifically in relation to dietary exposure assessments conducted by FSANZ and how they are used in this document. They may differ to how they are used by other risk assessors and dietary exposure assessments outside of FSANZ.

ADI	"An estimate of the amount of a chemical in food or drinking water, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable risk to the consumer" (FAO/WHO 2009ap. A-2). The ADI is listed in units of mg/kg bw/day.
Aggregate exposure	An estimate of exposure to a single food chemical considering multiple routes (oral, dermal, inhalation) and multiple pathways (food, drinking-water, residential) (FAO/WHO 2020a; Kennedy 2023).
Adequate Intake (AI)	The average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate (NHMRC et al. 2006 p. 1).
Application	Applications to FSANZ seeking to change the Australia New Zealand Food Standards Code are made by individuals, organisations or companies, whether from Australia, New Zealand or any other country.
Acute reference dose (ARfD)	The estimate of the amount of a substance in food or drinking water, expressed on a body weight basis, that can be ingested in a period of 24 hours or less, without appreciable health risk to the consumer (FAO/WHO 2009ap. A-3).
Consumer	Eaters of foods containing the chemical of interest or of foods proposed to contain the chemical of interest. Or, a consumer of a food of interest.
Consumer behaviour assessment	Assesses dietary exposure based on concentrations of the chemical in certain brands or foods, where the consumer may deliberately choose to select or avoid the food or chemical of interest.
Consumption	The amount of food and beverages consumed or eaten by populations or population sub-groups
Cumulative exposure	An assessment for two or more food chemicals that share a common mechanism of action, or synergistic or additive effects (FAO/WHO 2020a)
Deterministic exposure assessment	Methodology in which a single food chemical concentration is multiplied by a single food consumption amount for each food that contains the food chemical, with a single dietary exposure value being derived using a single body weight.

Dietary exposure	The estimated amount of a food chemical (other than a nutrient) that is ingested by a consumer from food, and/or dietary supplements.
Dietary intake	The estimated amount of a nutrient that is ingested by a consumer. from food and/or dietary supplements.
Dietary modelling	The mathematical techniques used to generate estimates of dietary exposure.
Estimated average requirement (**EAR)**	"A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group" (NHMRC et al. 2006 p. 1). Used to assess the adequacy of dietary intakes of populations.
Estimated dietary exposure	Dietary exposure assessments can only estimate (or model) the real situation with regard to dietary exposure to food chemicals. The reliability, accuracy and value of estimated food chemical dietary exposures are founded on the quality of the original data inputs (such as the food chemical concentration data and food consumption data) and the assumptions made through the assessment process
Exposure	The exposure to a chemical from all known sources including air, medicines, cosmetics and/or food depending on the chemical of interest.
Exposure assessment	The estimation of total exposure to a chemical from all sources including food, water, air and skin exposure. The third step in the risk assessment process.
Food	Includes solid foods, semi solid foods, beverages and water. Does not include dietary supplements (e.g. vitamin tablets).
Food chemical	Includes food additives, contaminants, natural toxicants, agvet chemical residues, nutrients, nutritive substances, novel foods and ingredients and other food chemicals (e.g. caffeine).
Food chemical concentration	Refers to the level or amount of a chemical in a set weight of food (e.g. 1 kg or 100 g). This may be at the raw commodity (e.g. milk), processed food (e.g. cheese), or 'as eaten' (e.g. pizza) food level.
Food consumption	Refers to the amount of food and beverages consumed or eaten by populations or population sub-groups, or groups of consumers.
Harvest	FSANZ's custom built computer application that is used to calculate dietary exposure to food chemicals.
Health-based guidance value (HBGV)	A level to which dietary intake or exposure estimates for the population are compared. Can indicate a level of essentiality or toxicity.
High consumer	An individual exposed at a higher level than the population average, as a result of consuming large amounts of a food, or foods with high levels of a food chemical, or many foods with average concentrations, or a combination of these.

Limit of detection (LOD)	The lowest concentration of a chemical that can be qualitatively detected using a specified laboratory method and/or item of laboratory equipment but not determined (i.e. its presence can be detected but not quantified).
Limit of quantitation (LOQ)	The lowest concentration of a chemical that can be detected and quantified, with an acceptable degree of certainty, using a specified laboratory method and/or item of laboratory equipment.
Limit of reporting (LOR)	The lowest concentration level that the laboratory reports analytical results.
Market weighted assessment	A concentration or exposure estimate that has the proportion of the market or food group that would be likely to contain the food chemical of interest taken into consideration, if it were approved for use.
Mean	Arithmetic mean (unless otherwise specified).
Maximum Level (ML)	The limit (expressed as milligrams per kilogram) placed on the level of a contaminant or natural toxicant, in food in the Australia New Zealand Food Standards Code. An ML is set at the lowest level that is achievable with good practices, while taking into account likely exposure to the contaminant in comparison to the TDI,TWI or TMI.
Model diet	"A type of screening method used in dietary exposure assessments that assumes fixed default consumption levels, usually for categories of foods and beverages" (FAO/WHO 2009a p. A-24).
Margin of exposure (MOE)	The ratio of the no-observed-adverse-effect-level (NOAEL) or benchmark dose (BMD) to the estimated dietary exposure (FAO/WHO 2009a).
Maximum permitted level (MPL)	The limit (expressed as milligrams per kilogram) placed on the level of an additive or processing aid, in food in the Australia New Zealand Food Standards Code. An MPL is set at the lowest level that achieves the technological purpose in the food.
Maximum residue limit. (MRL)	The highest concentration of a chemical residue that is legally permitted or accepted in a food or animal feed. The MRL does not indicate the amount of chemical that is always present in a treated food but it does indicate the highest residue that could result from the registered conditions of use. MRLs are not direct public health and safety limits but are indicators of whether an agricultural or veterinary chemical product has been used according to its registered use.
No observed adverse effects level (NOAEL)	"Greatest concentration or amount of a substance…that causes no adverse alteration of morphology, functional capacity, growth, development or lifespan of the target organism…" (FAO/WHO 2009a p. A-25)

Novel foods	Non-traditional foods or ingredients that require an assessment of public health and safety by FSANZ before being permitted for use and added to the food supply.
Point of departure	The NOAEL or BMD for a chemical that can be used to derive a HBGV or MOE.
Probabilistic dietary exposure assessment	A dietary exposure assessment methodology that involves using distributions of food consumption and food chemical concentration data to produce a distribution curve of potential exposures. Probabilistic modelling can take into account variations in food consumption patterns from individual to individual or day to day, variations in food chemical concentrations, and the variation in body weights across a population or population sub-group. Information on the likelihood and magnitude of the dietary exposures can be achieved using probabilistic methodology (Boon et al 2003).
Proposal	Proposals are prepared by FSANZ to consider changes to the Australia New Zealand Food Standards Code.
Respondent	Any person included in the NNS or other food consumption survey. The number of respondents will vary according to the survey (for example there were 12,153 respondents to the Australian 2011-12 NNPAS aged 2 years and above, and 4,721 respondents to 2008/09 NZANS aged 15 years and above). This term may also be used to refer to the number of respondents within a particular sub-population group.
Risk analysis	A process consisting of three components: risk assessment, risk management and risk communication (FAO/WHO 2009a).
Risk assessment	The scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.
Semi-probabilistic dietary exposure assessment	A dietary exposure assessment methodology which matches individual food consumption data with a single point chemical concentration per food or food group, to generate a distribution of individual dietary exposures.
Survey sample weights	The number of units in a population represented by a particular unit in a sample (for example a weight of 20 means that the sampled unit represents 20 units in the population). Survey sample weighting factors ('weights') are used to adjust survey data to better reflect the results that would have been obtained if a truly representative sample had been able to be obtained.
Theoretical maximum daily intake (TMDI)	"A prediction of the maximum daily intake of, for example, a pesticide residue, assuming that residues are present at the maximum residue level…and average daily consumption of foods per person…" (FAO/WHO 2009ap. A-37)

Tolerable daily intake (TDI) (or provisional PTDI)	"The reference value… used to indicate the safe level of intake of a contaminant with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and drinking water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI" (FAO/WHO 2009a p. A-28).
Tolerable monthly intake (TMI) (or provisional PTMI)	"An endpoint used… for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods" (FAO/WHO 2009a pp. A-28-29).
Tolerable weekly intake (TWI) (or provisional PTWI)	"The endpoint used… for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods" (FAO/WHO 2009a p. A-29).
Upper level of intake (UL)	"The highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases" (NHMRC et al. 2006 p. 1).
90th, 95th or 97.5th percentile	A level at which 10%, 5% or 2.5% respectively of the population or data points are above. The 90th percentile dietary exposure to a food chemical is generally used to represent a 'high consumer' in a chronic dietary exposure assessment.