Food Standards Australia New Zealand

Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes

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- Members of the Dietary Exposure Assessment Review Advisory Group (2007-2009)
- Members of the Dietary Modelling Stakeholder Advisory Group (1995-1997)
- Ms Ingrid Coles Rutishauser
- Dr Anne Cowling, Australian National University
- Dr Philippe Verger, French National Institute for Agricultural Research (INRA)

1. INTRODUCTION

1.1 Purpose and outline of this document

The purpose of this document is to:

- identify the principles 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 in applications, for the purposes of estimating dietary exposure.

Exposure assessment seeks to provide an estimate of the magnitude, frequency and duration of exposure to risk factors found in the environment. Dietary exposure assessments draw on food chemical concentration data and food consumption data from a range of sources, which are described in this document. Information is provided on the specific practices required for dietary exposure assessments for different types of food chemicals. In this document 'food chemical' refers to food additives, contaminants, agricultural and veterinary chemicals, nutrients, novel ingredients, processing aids, packaging migrants and other food chemicals (e.g. caffeine). This document does not include information on microbiological exposure assessments.

This document covers how FSANZ conducts dietary exposure assessments for Australia and New Zealand, as part of a risk assessment for food regulatory and related purposes. There are some instances where FSANZ will conduct dietary exposure assessments for Australia only, such as for agricultural and veterinary chemicals, because their use in New Zealand is not covered by the Australia New Zealand Food Standards Code ('the Code').

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 information about making applications to change the Code, you should refer to the *Application Handbook*, available at www.foodstandards.gov.au.

1.2 About FSANZ

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

The ultimate goal of FSANZ is a safe food supply and well-informed 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 for agricultural and veterinary drug residues.

In meeting its statutory obligations, FSANZ considers it 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.

1.2.1 The FSANZ risk analysis framework

The three basic steps of risk analysis were recognised at the Joint Food & Agriculture Organisation/World Health Organisation (FAO/WHO) Consultation on Risk Management and Food Safety held in Rome in 1997 (FAO/WHO, 1997a), and further articulated at a subsequent FAO meeting in 2005 (FAO, 2006). These basic steps are:

- risk assessment
- risk management
- risk communication.

The three steps work in practice in an integrated way as shown in figure 1.

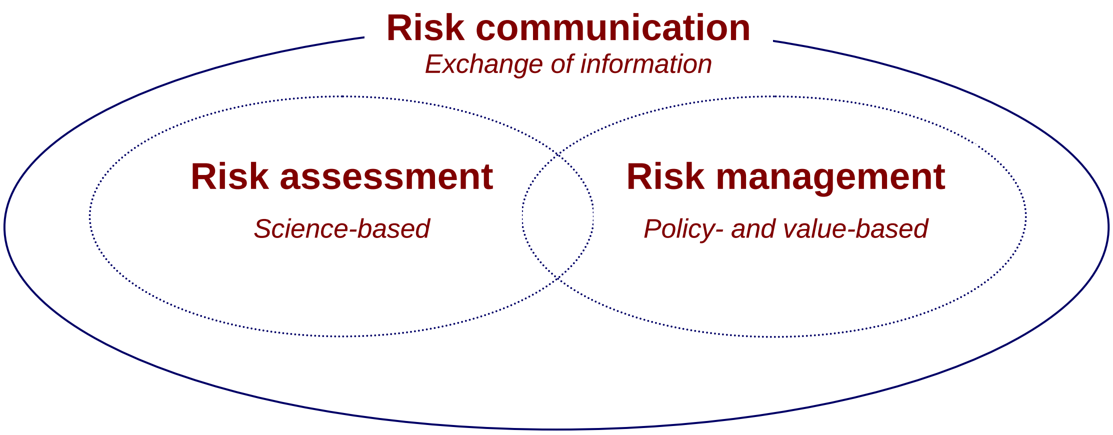

Figure 1. The Codex risk analysis framework

FSANZ recently released a document outlining risk assessment and risk management practices at FSANZ, *The Analysis of Food Related Health Risks* (FSANZ, 2009). The concepts and procedures described in the document are broadly consistent with those of other regulatory agencies and with principles established both by Codex under the Joint FAO/WHO Food Standards Programme and by the International Programme on Chemical Safety in cooperation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This document on dietary exposure assessment is intended to be used in conjunction with the broader FSANZ document *The Analysis of Food Related Health Risks* (FSANZ, 2009).

1.2.2 Risk assessment

A Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues (FAO/WHO, 1995a) was held in March 1995 in response to the establishment of the World Trade Organisation (WTO) agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). The Consultation agreed first on a number of definitions for food safety risk analysis and to a model for risk assessment. The model consists of four components (see figure 2):

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

The Analysis of Food-Related Health Risks provides more detail on the risk analysis framework used by FSANZ and on the other components of risk assessment.

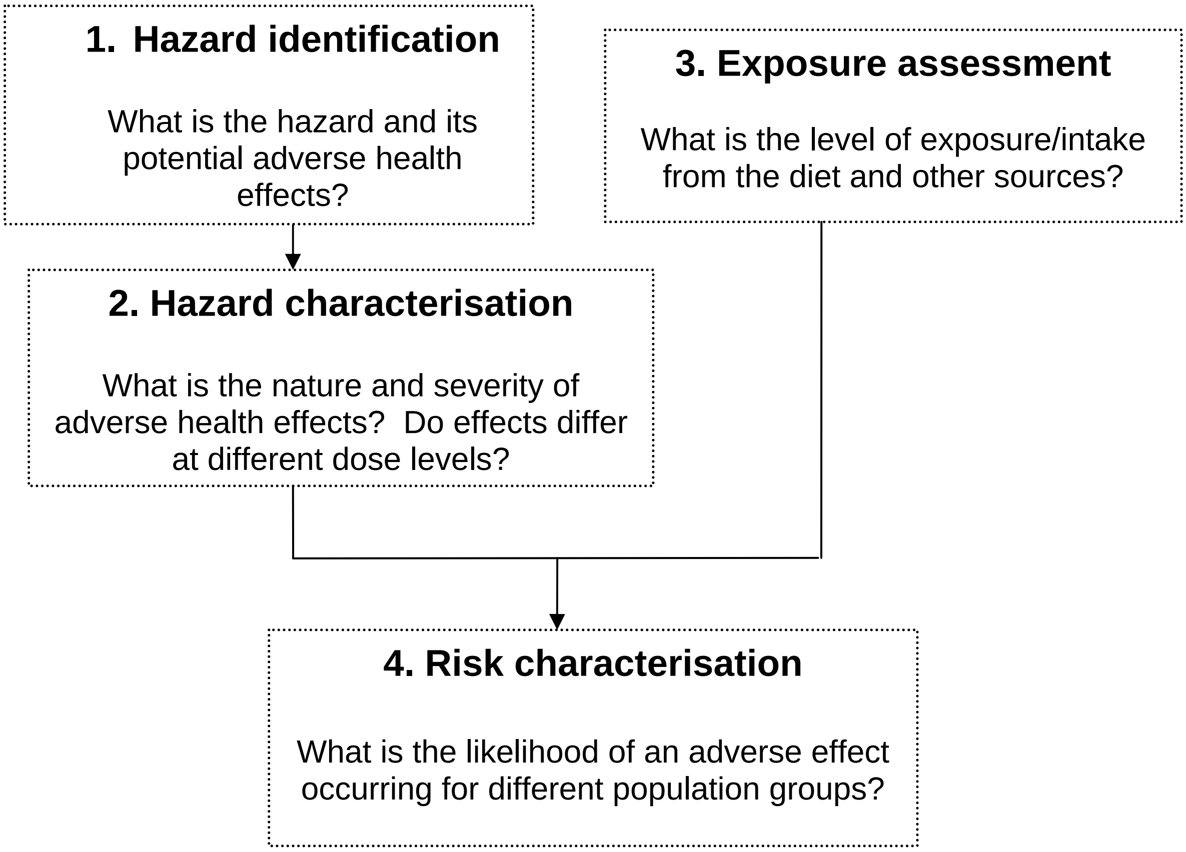

Figure 2. The four steps in risk assessment

1.2.3 Terms used

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 terms dietary 'exposure' assessment when referring to the assessments for all food chemicals apart from nutrients. 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 exposure estimates. Dietary modelling combines food consumption data with food chemical concentration data to estimate dietary exposure to food chemicals, or intake of nutrients. This is usually summed for all foods containing the food chemical and can be divided by body weight where assessments are being conducted for food chemicals for which toxicological effects are expressed on a body weight basis.

Dietary exposure = ∑(food chemical concentration x food consumption)

DIAMOND is FSANZ's custom made dietary exposure assessment computer program (see Appendix 1 for more details). DIAMOND (**DI**et**A**ry **M**odelling **O**f **N**utritional **D**ata) is used routinely by FSANZ staff but also offers flexibility to develop new dietary modelling approaches, with assistance from contract programmers. Therefore, the calculation capabilities for FSANZ dietary exposure assessments are extensive and adaptable.

In risk assessment, exposure estimates are compared with 'reference health standards', where available, to assess the potential risk to health associated with changes to the food supply. These reference health standards relate to the accepted level of exposure below which adverse health effects are considered not to occur. In the case of nutrients, for example, they may relate to the intake level the population should be reaching to achieve optimal health (see section 3.6). Where a population's dietary exposure is below the reference health standard (or above it in the case of a standard for nutrient adequacy), the likelihood of an adverse health effect is negligible.

Dietary exposure estimates may be for long term ('chronic') or for short term ('acute') exposures, the choice depending on the nature of the hazard posed by the chemical and the reference health standard established. Different concentration and food consumption data sets are required for each of these assessments (see section 4.4).

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' (consumers of foods containing the chemical).

By their very nature, dietary exposure assessments can only approximate (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.

1.3 How FSANZ uses dietary exposure assessments

FSANZ developed a dietary exposure assessment capability 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 contributions to Codex developments in risk assessment and management, in particular providing input into the 1997 and 2005 FAO/WHO consultations on exposure assessment, including development of guidelines for acute dietary exposure assessments (FAO/WHO, 1997b, FAO/WHO, 2008). FSANZ has also been directly involved in the incorporation of dietary exposure assessments into the risk assessment process undertaken by JECFA. FSANZ dietary exposure assessments are based on internationally established methodologies and developments at the international level are incorporated into FSANZ's principles and practices for dietary exposure assessments, where appropriate.

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 concerning food chemicals. Regulatory decisions are not, and should not, be wholly based on dietary exposure assessments. Many other issues are considered when making regulatory decisions, including, technological and economic issues and regulatory impact analysis (see *The Analysis of Food-Related Health Risks*, FSANZ 2008a).

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.

The major use of dietary exposure assessments at FSANZ is in food standards setting, as part of the assessment of Applications and Proposals to amend the Code. Dietary exposure assessments are used where required to assess the impact of permitting new food chemicals or extending permissions for use of food chemicals already in use. Changes in the food chemical composition of the food supply and changes in food consumption patterns can be used 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 on a range of different food chemicals such as pesticide residues, contaminants and food additives. Other 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 risk needs to be assessed. The concentration data from such surveys are used in dietary exposure assessments in order 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 modelling program enables food consumption data to be derived for any combination of foods at different levels of specificity for relevant projects. This information has been used in assessments for microbiological hazards and genetically modified foods for example, or to assist in interpreting dietary exposure assessment results.

In relation to risk management activities, dietary exposure assessments have been used in determining the need for food labelling (e.g. gastrointestinal effects from excess consumption of foods containing sugar alcohols) or in education campaigns (e.g. for mercury in fish).

There are some cases where dietary exposure assessments are unlikely to be useful. For example, the dietary exposure assessment techniques most commonly used at 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.

FSANZ inputs into dietary exposure assessments in the international arena. JECFA establishes safe levels of intake for food additives and contaminants and develops specifications for food additives. JECFA decisions are accepted internationally and are used by governments to assist in establishing national food standards. 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, as well as chemical concentration data at the national level. JECFA provides scientific advice to the Codex Committees on food additives and contaminants particularly in relation to the risk associated with particular levels of exposure to food chemicals of interest.

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, 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 maximum levels for food chemicals. This information is useful in establishing the Australian position used in discussion at the Codex meetings and in setting international food regulations.

1.4 FSANZ dietary exposure assessment review

During 2006 and 2007 FSANZ undertook a review of its dietary exposure assessments, including assessments of technical issues (such as data inputs and methodologies), communication issues (such as report writing and provision of information to stakeholders) and information and communication technology (ICT) issues (such as DIAMOND). An international expert in dietary exposure assessments was engaged to conduct the review, which was very positive in relation to all aspects of FSANZ dietary exposure assessment work. As part of the review, a number of recommendations were made to enhance this work. The report from the reviewer is available on the FSANZ website.

The peer review assessed FSANZ dietary exposure assessment capabilities in relation to international best practice. FSANZ was rated highly in relation to similar agencies in other countries that conduct dietary exposure assessments.

FSANZ also established an Advisory Group to provide input into the review. The group consisted of experts from areas relating to dietary exposure assessment methodologies, food consumption data, food chemical concentration data, statistics and ICT. Stakeholders from government departments, consumer groups and the food industry were also members of the group. The group provided input into the FSANZ dietary exposure assessment procedures, documentation, stakeholder information and ICT infrastructure. This Advisory Group continues to provide specialist advice to FSANZ.

2. FSANZ DIETARY EXPOSURE ASSSESSMENT PRINCIPLES

FSANZ has developed a number of principles that underpin our 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 modelling techniques should be no more complex than is necessary to answer the risk assessment questions.

- The most robust reference health standard permitted by the available data should be used in dietary exposure assessments. Wherever possible, reference health standards set by international food regulatory agencies or other reputable bodies, such as those set by JECFA, the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and the NHMRC will be considered in the first instance. If established reference values are current, robust and suitable they will be used for dietary modelling purposes in preference to *de novo* establishment of values by FSANZ. Where necessary, due to additional available data or identified flaws in established reference values, FSANZ will independently establish reference health values 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 end-point, as considered in the hazard characterisation (i.e. acute or chronic hazard). This may also affect the population groups included in the exposure assessment.

- Dietary exposure assessments should estimate the likelihood of some consumers having 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 adequacy).

- 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. This will facilitate understanding of the dietary exposure assessment outcomes for risk characterisation, risk management and risk communication purposes.

3. DATA SOURCES FOR DIETARY EXPOSURE ASSESSMENTS

There are two major data sources that are required in order to conduct dietary exposure assessments – food chemical concentration data and food consumption data. Food consumption data need to be grouped in ways that assist with exposure assessments. These and other relevant issues are discussed in this section.

3.1 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, and 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.

There are many different sources of food chemical concentration data, with major sources summarised in table 1 below.

Table 1. Summary of sources of food chemical concentration data

Food chemical type	Sources of concentration data
Contaminants	Maximum Levels (ML) in food standards Analytical survey data including compliance monitoring data Total Diet Study data Scientific literature including international databases
Agricultural and veterinary chemicals	Maximum Residue Limits (MRLs) in food standards Analytical survey and supervised trial residue data Total Diet Study data
Food additives, novel foods, processing aids	Maximum Permitted Levels (MPL) in food standards Manufacturer use levels Analytical/survey data Proposed levels of use
Nutrients	National food composition tables National nutrition survey data Analytical survey data Proposed or actual levels of use (fortification)
Packaging materials	Migration data
Flavourings	Manufacturers' use levels

The FSANZ dietary exposure assessment team has good linkages with the FSANZ food composition and surveillance areas. The teams collaborate in collecting and compiling data used for dietary exposure assessments. FSANZ will also collect data from other groups including state and territory government agencies, the food industry or universities for example, or from published scientific literature.

FSANZ prefers to use data from Australia and New Zealand for dietary exposure assessments, however sometimes such data are not available. In this case, data from other countries could be used, after assessment of its relevance to the Australian and New Zealand situation. For example, if a food is mostly imported into Australia/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. For contaminants 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 production conditions.

3.1.1 Maximum levels in food standards

In the absence of information on actual levels of chemicals in foods, FSANZ may use maximum levels established in the Code or in international regulations 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 reference health standard. If dietary exposure is estimated to be below the relevant reference health standard, there is unlikely to be a need to obtain more realistic concentration data. However if the worst case exposure approaches or exceeds the reference health standard, more realistic estimates of chemical levels (e.g. from analysed or manufacturers use data) can then be selected to provide a more realistic estimate of exposure.

3.1.2 Data derived from analytical surveys

Data quality

FSANZ has no set minimum data requirements. All data are assessed on a case by case basis in order to determine whether they are of adequate quality 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:

- 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?
- Survey design
  - Were the data from a broad ranging survey or from a survey targeted, for example, at likely non-compliant products?
  - Were the sample selection and collection methods representative and appropriate (e.g. appropriate consideration of factors such as geographical region, season, variety, brand, cooking method)?
- Analysis method
  - Was the method of analysis appropriate (e.g. a standard or validated method) or is there a much better method of analysis now available?

- Did the survey measure the chemical of interest?

- Number and range of data points
  - Are there sufficient data to 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)?

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.

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 food 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, information on variation in chemical concentration can be reduced as the analysed values will essentially be average values. This reduces the flexibility of the data for dietary exposure assessments based on probabilistic modelling techniques, and for acute dietary exposure assessments.

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. 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 broadly-based survey.

Treatment of not detected results

Within analytical data sets there may be concentrations of a food chemical that are shown as ‘not detected’ or are below the Limit of Quantification (LOQ) or Reporting (LOR) for the analytical method. For the purposes of an exposure assessment, FSANZ needs to assign them a numerical value to allow calculation of a representative concentration 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:

- value equal to zero (generally referred to as a ‘lower bound’ value)
- value equal to half the LOQ (‘ middle bound’)
- value equal to the LOQ (‘upper bound’)
- a range of values between zero and the LOQ.

Factors that will be considered on a case by case basis in deciding on the treatment of not detected results include the type of food chemical being assessed, whether it is deliberately added to foods or naturally occurring, whether essentiality and safety are being assessed, the number of not detected results and the magnitude of the limit of reporting in relation to the reference health standard (WHO/FAO, 2008).

FSANZ will report the method it has used in dietary exposure assessments to deal with not detected results and will attempt to identify the effect of this on likely exposure estimates.

Mode of expression of food chemical concentration data

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

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, or dried versus prepared. For example, a concentration value for 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 reference health standard. For example, nitrites are a food additive permitted for use in the Code as potassium or sodium nitrite. However, the health standard 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 are summed for one 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, of which 29 individual congeners have been identified as having a similar toxicological effect. Each individual chemical has a toxic equivalence factor (TEF) which ranks its toxicity in relation to the most potent chemical. 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.

Within the DIAMOND system, food chemical concentrations are expressed using the units mg/kg, except for nutrients, which by convention are expressed per 100 g. Therefore food chemical concentration data expressed in other units (e.g. µg/kg) must be converted to the units required by DIAMOND before dietary modelling commences.

Total diet studies

Total diet studies 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. Total diet studies are conducted in both New Zealand and Australia. FSANZ conducts only the Australian studies, with the New Zealand government conducting their country's total diet studies.

The purpose of total diet studies is to estimate the level of chronic dietary exposure of the population to a range of chemicals that may be found in the food supply. Traditionally, the Australian studies have focussed on dietary exposure to a range of agricultural and veterinary chemical residues and contaminants. However more recently, the focus of these studies has expanded to consider a broader range of food chemicals, including food additives and nutrients.

The reliability of total diet study data depends on the careful selection of foods and preparation methods, and inclusion of sufficient foods, so that the results are representative of the diversity of our food supply. Around 90-120 different foods are generally selected and these will be 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 the nation, at more than one time in the year. There is generally some compositing of samples so that the individual analytical results often will be averages of up to three sub-samples. Total diet studies analyse foods prepared as normally consumed, as opposed to raw commodities.

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 actual food preparation procedures used.
- 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 source of the food chemical; this can help to identify the food groups where more concentration data should be collected.
- The studies provide 'background' data in the event of local contamination.

Australian total diet study (ATDS) 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.

A limitation of total diet studies 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.

More information on specific total diet studies is available on the FSANZ website (http://www.foodstandards.gov.au/monitoringandsurveillance/australiantotaldiets1914.cfm).

Combining data from different surveys

Often FSANZ will 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 purpose and size of each data set, whether individual or composite values are reported, whether or not different data sets should be weighted, whether the same type and form of food had been analysed, and the analytical quality of each data set.

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 concentration data indicate a difference in levels in food eaten by that group compared to the same food that is consumed by the majority of the general population.

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 LOQs. There are several options for doing this, and the option selected will be carefully chosen to minimise sample bias and give the best possible data set for the purposes of the exposure assessment.

During the review of the Code in the late 1990s, selection criteria were developed to assist in determining what datasets could be used for dietary exposure assessment purposes and what representative food chemical concentration to use. These criteria can be found in Appendix 2 but are not necessarily exhaustive and may not be applicable in all circumstances, for example where little if any analytical data are available.

Appendix 3 provides an example of how chemical concentration data from different surveys were combined for the assessment of dietary exposure to mercury through fish consumption.

Selecting a concentration 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, dietary modelling may be conducted using a mean, median or high value derived from a data set.

In the usual semi-probabilistic approach to dietary modelling that FSANZ uses (see section 4.2.3 for further information), a single food chemical concentration value is selected for each type of food or food group included in the 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.

Median, mean and mode are statistical measures of central tendency that may be used to represent concentration levels in chronic 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 (see figure 3). Where the distribution of levels of food chemicals or nutrients is positively skewed, as is typically found in surveys of food contaminants, the median level rather than the mean level may be used in a dietary exposure assessment in order to avoid overestimating exposure.

In choosing a contaminant or agricultural and veterinary chemical concentration level for use in chronic dietary exposure models, 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 (WHO, 1997; FAO/WHO, 2008). However in some situations FSANZ may use the mean concentration, for example where analytical data exist for composite samples. A mean may be used because some averaging of the concentration has already occurred during the sample compositing process; this is usually the case for nutrients and results from total diet studies.

In acute dietary exposure assessments, a high concentration value is usually selected, for example, the highest residue reported for a pesticide residue in a food in an agricultural trial (see sections 4.4, 5.4.2).

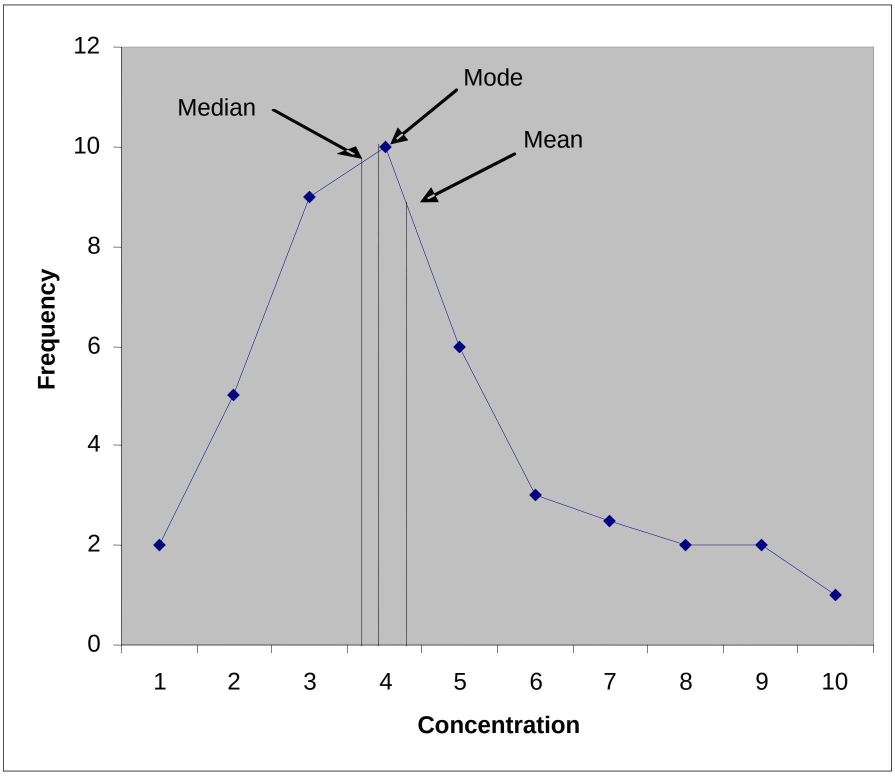

Figure 3: Measures of central tendency in a positively skewed distribution

3.1.3 Manufacturers' use levels

In many cases, particularly those relating to the assessment of food additives or novel foods, the only food chemical concentration data available to FSANZ for use in modelling will be data provided by the applicant or the food industry on the likely or actual levels of use of the chemical in question. These data would be used on the assumption that the amount added to a food would equal the amount remaining in the food as consumed. Again the mean, median, high concentration or maximum level added for a given food or food group may be selected depending on the purpose of the dietary exposure assessment.

3.1.4 Variability and uncertainty in food chemical concentration data

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 National Nutrition Surveys (NNSs). 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.

Three types of error, contributing to uncertainty, can be distinguished in most measurements (FAO/WHO, 2008):

- Gross errors refer to unintentional or unpredictable errors that occur while generating the analytical result, for example, contamination or deterioration of a sample before analysis. Gross errors invalidate the measurement and it is not possible or suitable to statistically evaluate and include data with gross errors in the estimation of measurement uncertainty.
- Random errors are present in all measurements and cause replicate results to fall on either side of the mean value. The random error of a measurement cannot be compensated for, but increasing the number of observations may reduce the magnitude of such errors.
- Systematic errors occur in most experiments. The sum of all the systematic errors in an experiment is referred to as the bias. They may go undetected unless appropriate precautions (e.g. use of standard reference materials) are taken.

Although increasingly, laboratories are expected to quantify the uncertainty associated with data they produce, most of the data already held by FSANZ does not have this additional information. Where possible, this information will be collected in future analytical programs.

Another source of uncertainty is the assignment of concentration data measured in one food to individual foods reported as consumed in NNSs. It is difficult to quantify the magnitude of this uncertainty but it is reduced by the use of appropriate recipes and translations in DIAMOND (see sections 3.5.4 and 3.5.5) and through staff experience and judgement. FSANZ will identify areas of uncertainty in dietary exposure assessment reports.

Table 2 provides an example of how FSANZ is likely to summarise major sources of uncertainty in a dietary exposure assessment, using the example of an assessment of intake of fatty acids.

Table 2: Example of a summary presentation of the qualitative evaluation of the impact of uncertainties on the assessment of intake of fatty acids

Sources of uncertainty	Direction and magnitude*
Uncertainty in analytical results, particularly at low concentrations	+++/---
Influence of non-detects in analysis	+/-
Small analytical data set	++/--
Uncertainty in assigning foods to concentration categories and developing concentrations for mixed foods	++
Use of 24 hour food consumption recall data to assess habitual intake	+/-
Age of food consumption data	+/-

* +, ++, +++ represent uncertainty with potential to cause small, medium or large over-estimation of intake
-, --, --- represent uncertainty with potential to cause small, medium or large under-estimation of intake

3.2 Food consumption data

The use of appropriate food consumption data in dietary exposure assessments is obviously extremely important. There are many methods that can be used to collect food consumption data with the type of food chemical and the purpose of the assessment determining the most appropriate source of data.

3.2.1 Surveys on consumption for individuals

The best data for conducting dietary exposure estimates are food consumption data collected from individuals. There are many different ways to do this. A key consideration for FSANZ is that data used should be representative of the population group being assessed.

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 Australian and New Zealand NNSs, and in nutrition surveys in many other countries. In a 24-hour recall survey, each individual is interviewed and the foods eaten and amounts consumed are recorded for the previous 24-hour period. These surveys rely on people remembering what they consumed and estimating the amount consumed, although good survey design assists with the accuracy of this information. In some surveys a second, non-consecutive 24-hour recall may also be conducted for some or all respondents.

A food record (also sometimes called a diary) is a method that requires individuals to weigh or record all foods eaten and the amounts consumed as they eat it, over a number of days (usually one, three, seven or 14 days). These surveys may be more accurate than 24-hour recalls in recording all foods and consumed and amounts, although respondents may change their eating habits to make it easier to weigh foods and there is a higher respondent burden for this type of survey. Nevertheless 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 a particular food or small group of foods than can be provided in a 24-hour recall.

The advantages of using individual food consumption data are:

- 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
- dietary exposures for different population sub-groups can be estimated
- dietary exposure of consumers at low and high points of the distribution can be assessed to represent low or high consumers
- scenarios of food chemical concentrations can be modelled to predict exposure under different risk management options.

The disadvantages of using individual food consumption data include:

- the data are expensive to collect (although in Australia and New Zealand they have been collected anyway for other purposes)
- their use is more time consuming than use of data from screening techniques and requires more technical expertise and an effective information technology system
- critical groups may not be adequately represented (e.g. infants).

Food frequency questionnaires (FFQ) record how often an individual eats certain foods, usually over the previous 12 months. FFQs may also collect semi-quantitative estimates of foods consumed but will rarely cover the diversity of foods consumed by a population. Generally FFQs do not provide adequate data for FSANZ's dietary exposure assessment purposes because there is insufficient detail on specific foods eaten and on the amount consumed. However their results may be used to help interpret findings based on 24-hour recalls. 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.

Short questions are often included when collecting food consumption data from individuals. These questions collect data on food habits such as addition of fat during cooking, types of fats and oils used (e.g. 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 data.

When using food consumption data for individuals, it is important to clearly distinguish between a whole population's exposure to a food chemical (exposure averaged across all survey respondents regardless of whether or not they had any exposure) and the exposure of consumers only (exposure of the sub-set of a population that consumed foods containing the chemical of interest, thus excluding those who had no consumption or exposure).

National nutrition surveys - Australia

The 1995 NNS provides comprehensive information on dietary patterns of a sample of 13,858 Australians aged from 2 years and above (McLennan and Podger, 1998a). It is the most recent NNS for Australians aged above 16 years. The survey used a 24-hour recall method for all respondents, with 10% of respondents also completing a second 24-hour recall on a second, non-consecutive day. Food frequency data are available for a subset of the national sample (respondents aged 12 years and above) as are responses to a series of short dietary questions about food habits. The Australian Bureau of Statistics (ABS), who conducted the survey in conjunction with the Department of Health and Aged Care, released some publications from the NNS including a Users' Guide (McLennan and Podger, 1998a), a summary of selected highlights (McLennan and Podger, 1997), a summary of food consumption data (McLennan and Podger, 1999) and a summary of nutrient intakes and physical measurements (McLennan and Podger, 1998b).

FSANZ uses the 1995 NNS as the current basis for most dietary exposure assessments for Australians. Individual, confidentialised records are used for this purpose, rather than aggregated population statistics reported in the summary publications noted above.

A NNS for Australian children aged 2 to 16 years was conducted in 2007 (the 'Kids Eat Kids Play' Survey), with the results released in late 2008 (CSIRO, 2008a). Two non-consecutive 24-hour recalls were collected from each of the approximately 4,400 respondents as well as physical activity records. Dietary supplement use was quantified in addition to food and beverage consumption. Some short questions were included but there was no food frequency questionnaire. FSANZ began to use the results of this survey in mid-2009.

National dietary surveys in Australia were also conducted in 1983 on adults (Commonwealth Department of Health, 1986) and 1985 on schoolchildren (Commonwealth Department of Health, 1988) and were limited to the 25-64 year (6,255 respondents) and 10-15 year (5,224 respondents) age groups respectively. The 24-hour dietary recall method was used in the 1983 survey, and a one-day record in the 1985 survey. FSANZ has the raw data from these surveys and used them as the basis of the DIAMOND program when it was first developed. However these data are no longer routinely used.

Table 3 summarises some key features of each of the NNSs used regularly by FSANZ.

National nutrition surveys – New Zealand

FSANZ uses the results of the 1997 NNS that questioned 4,636 adults aged 15 years and above (Ministry of Health, 1999) in its dietary exposure assessments. There was over-sampling of Maori and Pacific people, ensuring over 700 Maori and over 300 Pacific participants. This was done in order to obtain robust estimates of dietary intake and nutritional status for these ethnic groups. A similar 24-hour recall methodology to the Australian NNS was used with 15% of respondents reporting a second 24-hour recall, along with an FFQ for all respondents.

The 2002 New Zealand Children's Nutrition Survey (CNS) was also conducted similarly and collected data from 3,275 children aged 5-14 years (Parnell et al, 2003). Consumption of dietary supplements was recorded. FSANZ began to use the results of this survey in mid-2009.

Another national dietary survey is the 1989-90 Life in New Zealand (LINZ) Survey, completed by the University of Otago (1991). The aim of that survey was to provide information on major lifestyle factors, including nutrition. The LINZ survey sampled adults aged 15 years and above and used a 24-hour dietary recall and two FFQs. These data are not usually used by FSANZ.

Other national surveys

In August 1995, the then ANZFA contracted the ABS to collect data on nutrient supplement usage among a representative sample of Australian adults. These data complement the data collected in the 1995 NNS.

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 food groups and/or population groups. For example, in 2003 FSANZ commissioned a survey of consumption of intense sweetened foods in Australia and New Zealand, focussing on the population group who are high users of these foods (FSANZ, 2004a). This survey involved a screener survey of people aged 12 years and over to identify high users, followed by a seven day diary survey of food consumption, reported by brand and flavour, of 400 high users and another 298 individuals with diabetes or impaired glucose tolerance. This survey repeated a similar one conducted in 1994 for Australia only (NFA, 1995).

Information on surveys on specific population subgroups in New Zealand are summarised in an MOH report on food and nutrition monitoring systems (MOH, 2003b).

Market research companies may also provide data collected for other purposes to FSANZ on a fee-paying basis. For example FSANZ has access to the Roy Morgan Research *Single Source* (Australia and New Zealand) and *Young Australians* food frequency survey data and data on attitudes to foods, from 2001-2008. These data are not able to be directly integrated into the quantitative assessments produced using DIAMOND, but are used instead to supplement or qualify the data from NNSs and validate assumptions made in models.

Non-national surveys

FSANZ may at times use data from quantitative surveys of population sub-groups, rather than national surveys, to assist with specific dietary exposure assessments. These may include state-based surveys in Australia or surveys of health interventions where dietary information was collected (e.g Australian Longitudinal Study of Women's Health, see http://www.alswh.org.au/).

Food consumption data are available from food frequency and food habits surveys for some states (e.g. Victoria) (CSIRO, 1993) and for some smaller population subgroups, in particular for the aged (Baghurst, 1991) and migrant groups (Webb & Manderson, 1990; Kouris-Blazos et al, 1996; Renzaho and Burns, 2006). In the past, the NHMRC has used State based food frequency data in dietary models when considering food fortification issues. In recent years, some States have conducted 24-hour recalls or food habit surveys with children (e.g. Abbott et al, 2007; Booth et al, 2006).

FSANZ expects to have access to consumption data for infants under two years of age in two Australian centres, collected as part of the NOURISH study currently being conducted through Queensland University of Technology's Institute of Health and Biomedical Innovation. The first set of data should become available for use in 2010.

Table 3 Features of National Nutrition Surveys (NNSs) used in FSANZ dietary exposure assessments

Feature	Australia		New Zealand	
	1995	**2007**	**1997**	**2002**
Age group (years)	2 years and above	2-16 years	15 years and above	5-14 years
Number of respondents	13,858 total (2,729 aged 2-16 years)	4,487	4,636	3,275
Duration	12 months January 1995 – January 1996	7 months February 2007 – August 2007	12 months December 1996 - November 1997	10 months Late February to mid December
Survey sampling frame	Area-based, stratified sampling based on census districts Up to two (urban) or three (rural, Qld) respondents from each selected household	Stratified quota sampling with non-proportional samples Minimum 1000 children (50:50 M:F) in each of 2-3, 4-8, 9-13 and 14-16 year age groups Booster sample (n=400) in South Australia Non-random selection of single respondent per household	Area-based, stratified sampling Additional sampling to boost Maori and Pacific people's sample Random selection of a single respondent within selected households	School-based sampling with non-proportional samples Quota of approx 1000 children in NZEO, Maori and Pacific groups
Survey method used	1 x 24 hour recall 10% second 24 hour recall	2 x 24 hour recall - all respondents (day 1 face to face, day 2 by telephone)	1 x 24 hour recall 15% second 24 hour recall	1 x 24 hour recall 15% second 24 hour recall
Other survey features	Food frequency questionnaire (12 yrs+) Short questions on food	Short questions on food Quantified dietary supplement use	Food frequency questionnaire Short questions on food	Food frequency questionnaire Short questions on food Quantified dietary supplement use

Feature	Australia		New Zealand	
	1995	2007	1997	2002
Method of adjusting for long term nutrient intake	Statistical adjustment technique described by ABS (Rutishauser, 2000)	Each individual's intake is averaged over two days	Statistical adjustment technique described by ABS (Rutishauser, 2000)	Statistical adjustment technique described by ABS (Rutishauser, 2000)
Method of adjusting for long term food consumption or exposure (other than nutrients)	Not generally possible 90^{th} percentile used to represent high consumer	Each individual's exposure or consumption is averaged over two days 95^{th} percentile used to represent high consumer	Not generally possible 90^{th} percentile used to represent high consumer	Not generally possible 90^{th} percentile used to represent high consumer
Use of sampling weights by FSANZ	Not used in DIAMOND as sample broadly representative of total population	Used in DIAMOND as survey sample was not representative across ages (particularly the large oversampling of 2-3 year olds)	Not used in DIAMOND. Survey slightly oversampled Maori & Pacific people but not considered significant in terms of intake assessment outcomes	Used in DIAMOND as survey sample was not representative across ethnic groups (oversampling of Pacific people and, to a lesser extent, Maori)
Reference	McLennan & Podger (1998a)	CSIRO (2008b)	Quigley & Watts (1997)	Parnell et al (2003)

3.2.2 Model diets

Where no consumption data for individuals are available, a model diet (also referred to as 'simulated' or 'theoretical' diets) may be constructed to represent a 'typical' diet for a given population group.

The advantages of the model diet approach are that it:

- is cost effective
- can take different population sub-groups into account
- can take different chemical levels into account
- is useful when limited data are available.

The disadvantages of the model diet approach are that:

- it is subject to error when many foods are involved
- the outcome is very dependent on assumptions made
- it does not account for individual variation in consumption.

Australian children aged less than 2 years

There are no data available from the 1995 Australian NNS for children aged less than 2 years. Therefore FSANZ constructs a model diet to prepare a dietary exposure estimate for very young children. This is often done for a three month old infant (purely breast or formula fed), a nine-month old infant (e.g. for use in the ATDS) or for a one year old child consuming a combination of milk/formula/breast milk and other solid foods and beverages. These model diets are constructed by using the recommended energy intakes as defined by the WHO, usually for boys at the 50th percentile weight (WHO, 2006a, FAO, 2004) as they have higher energy needs per kilogram of body weight than girls of the same age.

For model diets for 3 month olds, consumption amounts also take into account the energy requirements of infants and the energy content of breast milk or formula. For model diets for 9 month infants, it is assumed that 50% of energy intake is derived from breast milk or formula and 50% from all other foods (including non-milk beverages) while for 12 month infants, it is assumed that 35% of energy is from breast milk/formula with the remainder from other foods (Hitchcock *et al*., 1986). The patterns of solid food consumption of a two-year-old child from the 1995 NNS, derived using DIAMOND, are scaled down in proportion to energy intakes and used to determine the solid portion of the model diet. Certain foods such as nuts (excluding peanut butter), coffee and alcohol are removed from the diet since nuts can be a choking risk (NHMRC, 2003) and coffee and alcohol are unsuitable foods for infants (ACT Community Care, 2000).

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 in the infant 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 (Office of Premarket Approval, 1995) of:

$$90^{th} \text{ percentile exposure} = \text{mean exposure} \times 2$$

New Zealand children aged less than 5 years

As there are no data available from NNSs for New Zealand children aged less than 5 years, a model diet is used to estimate their dietary exposures. Simulated diets for 1-3 year old toddlers were used in the analysis of the 2003/04 New Zealand Total Diet Survey (NZ TDS) (Vannoort and Thomson, 2005) and have been used by FSANZ for dietary exposure assessment purposes. The simulated diet was a 14-day diet constructed to represent average consumers and was derived from regional studies, rather than national studies of food and nutrient consumption (Vannoort and Thomson, 2005).

The New Zealand model diet has the same limitations as the Australian model diet in not being able to determine a distribution of exposures.

3.2.3 Per capita consumption (food balance sheets)

Per capita consumption data can be used to estimate an average population exposure to a food chemical. Food balance sheets give per capita estimates of national food availability. These food supply data sum national food production and imports and account for exports and non-food use but do not take household food waste and intra-household food distribution into account. They therefore tend to over-estimate food consumption, and hence dietary exposure, by around 15% compared to individual survey estimates (FAO/WHO, 2008).

The advantages of using per capita data include:

- data may be readily available
- they 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
- their use is cost effective.

The disadvantages of per capita data include:

- mean dietary exposure for the whole population is over-estimated
- they rely on accurate demographic and food balance sheet data
- they cannot be used for population sub-groups or 'non-average' consumption patterns and may underestimate dietary exposure for these groups
- they can really only be used for dietary exposure estimates based on raw and semi-processed commodities, for example for contaminants and agricultural chemicals.

FSANZ rarely uses this approach for standards development purposes as NNS data are available and up-to-date national food balance data for both Australia and New Zealand are no longer available.

In Australia, the Australian Bureau of Statistics (ABS) used to compile food balance sheets in the form of *Apparent Consumption of Foodstuffs* on an annual basis, although this has been discontinued since the 1998/99 report. Information on total food available for consumption and per capita is provided for major commodities, including beverages. The ABS undertakes a Household

Consumption Survey (HCS), which includes limited information on foods purchased by households; FSANZ also has access to data on food imports into Australia (ABS, 2009).

In New Zealand, Statistics New Zealand was responsible for the production of annual food balance sheets, which were published until June 1996. Data were collected from regular agricultural and horticultural surveys and from individual production surveys, as well as from producer boards and associations. Statistics New Zealand also conducts a Household Economic Survey (HES) every three years to provide data on expenditure patterns, income, social and demographic statistics, which includes data on food purchases (Statistics New Zealand, 2003).

International per capita data – GEMS/Food Consumption Cluster Diets

Food balance sheets continue to provide a useful tool at the international level. FAO/WHO publish per capita food consumption data, where countries are clustered according to consumption of the main staple(s) (WHO, 2006b). There are 13 clusters in the current set of diets. Data are compiled from the FAO's food balance sheets, though for developed countries food consumption survey data may also be included. The GEMS/Food Consumption Cluster Diets are available from http://www.who.int/foodsafety/chem/gems/en/index1.html.

The Cluster Diets may have a role in dietary exposure assessment at the 'per capita' level in Australia and New Zealand where apparent consumption data could be used to represent different dietary habits for ethnic groups, whose diets are based on different staples originating from major world regions. Although information on dietary habits for ethnic groups is available from the 1995 Australian, 1997 and 2002 New Zealand NNSs, data on region of birth does not indicate whether or not traditional dietary patterns are followed by individuals.

GEMS/Food Consumption Cluster Diets are used as model diets by JECFA and JMPR for estimating mean chronic dietary exposure to contaminants and pesticide residues. Separate diets are available for use internationally for acute dietary exposure estimates. These are based on consumption of foods at the 97.5th percentile, for consumers only, in six developed countries, including Australia and New Zealand.

3.2.4 Uncertainty in food consumption data

NNS food consumption data do not necessarily provide a fully accurate representation of the actual foods survey respondents have eaten, or the amounts eaten. For example, respondents may not know the type of milk, oil or meat they have eaten, may have eaten a mixed food that contained ingredients they weren't aware of or may not have known how big their cup of coffee was. In all these cases, the survey managers will have made assumptions about what was actually eaten. This introduces random error. Across a whole survey group, which is typically thousands of people, these assumptions may be of no significance in determining population mean food consumption.

The design of a survey can introduce systematic error. 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 were assigned a mass of 350 g instead of 250 g, average coffee consumption would be overestimated). There may also be a tendency for respondents to over-estimate consumption of foods perceived as 'good' and under-estimate consumption of 'bad' foods (FAO/WHO, 2008).

There is further uncertainty when a food of interest in a dietary exposure assessment was not reported as being consumed in the NNSs. This may be the case for foods that have only become available since the last NNS or that have become more widely consumed since that time. FSANZ must then decide on the most appropriate substitute food to use for modelling purposes.

FSANZ presents qualitative information about the uncertainty associated with food consumption amounts in dietary exposure assessment reports.

3.3 Demographic and related data

There are two demographic variables provided from NNSs that are used regularly in FSANZ dietary exposure assessments: age and gender. 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.

Geographic location is not used in FSANZ dietary exposure assessments, other than in separate reporting of exposures in Australia and New Zealand. The 1995 NNS did not include sufficient sample in some of the smaller states and territories to allow valid inter-state comparisons for individual foods. In addition, the same food standards apply in all states and territories of Australia and therefore 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.

Body weights are used for assessments where reference health standards (see below) are expressed on a body weight basis. In such cases, individual dietary exposure is adjusted for individual body weight before derivation of statistics for a population's dietary exposure expressed on a body weight basis.

3.3.1 Sampling 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. Some population groups, such as young adults, people who live in remote areas, are indigenous, 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. 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. Survey sample weighting factors ('weights') are used to adjust the results of surveys 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, gender, location and ethnicity.

Deliberate over-sampling of some population groups is found in the New Zealand NNSs where Maori and Pacific people have been over-sampled in proportion to their share of the New Zealand population (Quigley and Watts, 1997; MOH, 2003a). As a result, there may be bias towards these population groups in FSANZ dietary exposure assessments based on the 1997 NZ NNS because population weights are not used[1]. Appropriate weights will be applied to the 2002 NZ children's

[1] In the 1997 New Zealand NNS, respondents completing the second 24-hour recall were selected from urban areas only, to reduce costs (Quigley and Watts, 1997)

NNS data as the over-sampling of Maori and Pacific people was marked in that survey. The weighting technique used in DIAMOND is explained in Appendix 1.

In the 2007 Australian children's survey, sample numbers were selected to obtain roughly equal numbers in each of the age groups used for nutrient reference values (NRVs) and therefore the proportion of young children (2-3 years), in particular, is higher than in the general population. Population weights are used by FSANZ with this survey where relevant. The Australian 1995 NNS data are not particularly skewed towards one population group, and similar estimates of nutrient intake are produced through DIAMOND using unweighted data as the published results that were developed using weighted data.

Use of population weights will be identified in dietary exposure assessment reports and may be applied to individual's food consumption amounts (in the case of reports of food consumption) or resultant dietary exposure, depending on the purpose of the assessment.

3.4 Other data used in dietary exposure assessments

There may be other data sources that FSANZ uses to assist with dietary exposure assessments. These may include market share information for food products, or consumer research data on consumption behaviours and attitudes. 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.

3.4.1 Market share data

Actual or projected market share data for products that contain, or are proposed to contain, a food chemical are useful for some dietary exposure assessments. Information on the specific food products most likely to contain a chemical such as an additive, nutrient or a novel food, is also useful. Market share data may be derived from industry reports (e.g. Retail Media, 2007), directly from the food industry or from observation.

FSANZ uses this type of information to:

- more clearly identify the foods that are likely to contain the food chemical
- adjust chemical concentration levels to take into account the likely long term mean chemical level in a food category to reflect the overall food supply
- more clearly identify the population groups that are most likely to consume the foods containing the chemical
- determine if there has been a significant change in consumption of a product category since the NNS data were collected
- develop scenarios of possible market shares 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 4.6 contains more detail about conducting a market-weighted dietary exposure assessment.

3.4.2 Consumer research data

Data from research into consumer attitudes and behaviours can be useful in conducting some dietary exposure assessments. As with market share information, consumer research can help to establish modelling scenarios and to interpret 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 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. Obviously, data relating to Australia and New Zealand are the most useful.

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 of coloured water-based beverage.

Section 4.7 contains more information about conducting a consumer behaviour dietary exposure assessment.

3.5 Food classification systems

National nutrition surveys have traditionally classified foods into food groups that were similar to food selection guide food groupings and were useful for reporting sources of nutrients in diets. Each food in a nutrition survey is given a unique food code. The food codes are in a hierarchical format based on food groupings. Figure 4 shows an example of a food classification system used for nutrient assessments.

```
12 = Cereal and cereal products
  121 = Flours, and other cereal grains
      1211 = Grains (other than rice)
            12110001 = Barley, pearl, raw
            12110051 = Barley, pearl, cooked
```

Figure 4. An example of the food coding system for the 1995 Australian NNS

Nutrient intake assessments are conducted based on individual foods reported in NNSs and no further coding system is required as each food reported is assigned a unique nutrient line.

For the purpose of dietary exposure assessments for 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. Code permissions for levels of food chemicals are generally assigned to a group of similar foods and therefore the myriad of foods reported as consumed in NNSs must be assigned to the correct food groups to ensure the dietary exposure assessment is accurate. In the DIAMOND program, foods are grouped into categories appropriate for the assessment of processed foods or raw commodity groups, or may be used ungrouped.

3.5.1 Processed food classification system

For the risk assessment of food chemicals such as food additives or novel foods, the processed food classification system used is the Australia New Zealand Food Classification System (ANZFCS), from Standard 1.3.1 Food Additives. This system classifies foods into groups according to potential additive use in both fresh and processed commodities and has been adapted from the International Confederation of Food and Drink Industries (CIAA) classification system. A similar classification is used in the Codex General Standard for Food Additives (GSFA). An example of some of the ANZFCS codes and food group descriptions is provided in figure 5.

1	DAIRY PRODUCTS (excluding butter and butter fats)
1.1	Liquid milk and liquid milk based drinks
2	EDIBLE OILS AND OIL EMULSIONS
4	FRUITS AND VEGETABLES (including fungi, nuts, seeds, herbs and spices)
4.1	Unprocessed fruits and vegetables
4.3	Processed fruits and vegetables

Figure 5. An example of the codes and food group descriptors from the Australia New Zealand Food Classification System from Standard 1.3.1 Food Additives of the Australia New Zealand Food Standards Code

3.5.2 Raw commodity classification system

For the assessment of dietary exposure to agricultural and veterinary chemical residues or contaminants, it is most appropriate for foods to be classified into raw commodity groupings. The classification system used by FSANZ is based on a modified Codex Committee on Pesticide Residues (CCPR) commodity system (CCPR, 1992), as given in Standard 1.4.2 Maximum Residue Limits, Schedule 4. In addition, to take account of contaminants found in processed foods, the Codex Committee on Contaminants has developed a complementary food classification system for use in the Codex General Standard on Contaminants. The food groupings in both classifications distinguish foods derived from animal and plant sources.

For agricultural and veterinary chemicals where use is restricted and the chemical is registered for only one or a few foods within a given food group, it may not be valid to classify foods or commodities into large food groups. 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. However, 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 is shown in figure 6.

CF Cereal grain fractions
FB Berries and other small fruits
FB0021 Currants, black, red, white
FB0204 Blueberries
FB0264 Blackberries
MM Meat mammalian
MM0812 Cattle meat
MM0817 Kangaroo meat
MM0822 Sheep meat

Figure 6. An example of the codes and food group descriptors from the raw commodity classification system, from Standard 1.4.2 Maximum Residue Limits of the Australia New Zealand Food Standards Code

3.5.3 Translations or mapping

As a consequence of needing to conduct modelling based on food classification systems such as those set out above, a major step in conducting dietary exposure assessments is matching (also called 'translating' or 'mapping') the individual NNS foods to the food groups in the food classification systems outlined above. Then a single food chemical value for a group of foods can be assigned to all foods that are matched to this code. For example, green apples and red apples, peeled or unpeeled, would be translated to the raw commodity code for apples; or cheddar cheese, mozzarella cheese and all other types of ripened cheeses can be grouped in the single food additive code for cheese and cheese products.

Although DIAMOND pre-groups foods into appropriate groups for the majority of food additive and raw commodity exposure assessments, at times different translations may be required to meet the needs of a specific exposure assessment, for example, to distinguish sugar sweetened products from those containing intense sweeteners.

3.5.4 Recipe data files

Many individual foods from an NNS, such as mixed foods, do not directly match one of the food classification codes used in DIAMOND. Recipes are used for mixed foods to divide the food into component ingredients. Separate recipes are conducted to apportion ingredients under the processed commodities 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 only 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 in DIAMOND for nutrient intake assessments.

3.5.5 Hydration and raw equivalence factors

Hydration and raw equivalence factors are applied to some foods 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 for food additives, raw commodities for contaminants and pesticides). Factors are only applied to individual foods as consumed on the day of the nutrition survey, and not major food group codes. For example, an amount of cordial as syrup reported in the NNS is converted to an amount of prepared cordial for food additive modelling, or an amount of cooked meat reported in the NNS is converted to raw meat for modelling using raw commodities.

Conversion factors of these kinds are based on many sources of data including instructions for product preparation, food composition information, weight change factors, processing information and protein contents, to name a few (FSANZ, 2008).

3.6 Reference health standards

The final step in the risk assessment framework is a qualitative or quantitative estimation of the probability of occurrence and severity of known or potential adverse effects in a given population, based on the preceding steps of hazard identification, hazard characterisation and dietary exposure assessment (see *Analysis of Food Related Health Risks*, FSANZ, 2008a). For convenience, FSANZ dietary exposure assessment reports generally include a comparison of dietary exposure against the relevant reference health standard.

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

- For food additives and agricultural and veterinary chemicals, the reference health standard 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 substance in food or drinking water, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable risk to health (FAO/WHO, 2006).
- For contaminants, the reference value used to indicate the safe level of chronic exposure to a contaminant is the so-called 'tolerable intake' or ‘provisional tolerable intake’, which can be calculated on a daily, weekly or monthly basis. The tolerable intake is defined in the same way as the acceptable intake for additives but use of the term ‘tolerable’ indicates that contaminants are not deliberately added to foods (WHO, 2008).
- 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 the chemical in food, expressed on a bodyweight basis, that can be ingested during one meal or one day, without appreciable health risk to the consumer (WHO, 2008). ARfDs are generally set only for some agricultural and veterinary 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.
- For nutrients, there are several reference health standards that can be used, and these are generally based on the Nutrient Reference Values (NRVs) established by the NHMRC (2006):

- *Estimated average requirement (EAR)* – the daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group. This is the measure of population adequacy that FSANZ uses in risk assessments.
- *Recommended dietary intake (RDI)* - the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group.
- *Adequate intake (AI)* - the average daily nutrient intake levels 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) and *Suggested Dietary Target* (SDT) are two other NRVs that may sometimes be used in risk assessments.

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

3.6.1 Chemicals with no reference health standard

For some food chemicals assessed by FSANZ, no formal reference health standard has been established, for example for some novel food ingredients or for genotoxic carcinogens.

For genotoxic and carcinogenic chemicals a margin of exposure (MOE) approach is generally used. The MOE is the ratio of the no-observed-adverse-effect-level (NOAEL) or benchmark dose (BMD) to the estimated dietary exposure (see *Analysis of Food Related Health Risks*, FSANZ 2008a).

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

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. Alternatively, it may not be possible to complete a risk characterisation step, in which case the dietary exposure assessment report will omit this component.

Dietary exposure estimates for chemicals without reference health standards may still be useful. For example, they may be used to compare the relative importance of exposure via food with other exposure routes when determining risk management options, or to compare exposures estimated by FSANZ to those in other studies.

4. 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 a number of things need to be considered including:

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

The answers to the points above will determine the type of dietary exposure assessment required and the technique that will be used.

4.1 Tiered or stepwise approaches to exposure assessment

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.

In a tiered approach to dietary exposure assessment, the initial assessment will tend to be very conservative and often used as part of a screening process. It is used to identify chemicals for which more detailed exposure assessments are warranted. If a screening assessment shows a potential for a safety concern, more refined dietary modelling techniques may be used to produce a more refined and realistic estimate of dietary exposure. These more refined estimates can result from improved or more detailed consumption data, improved or more detailed concentration data, more sophisticated modelling techniques, or a combination of these.

Modelling techniques available to use in a tiered approach range from screening techniques such as the budget method, through deterministic to probabilistic modelling techniques. Each of these are outlined below. The tiered approach as used by FSANZ is illustrated in figure 7.

In practice, screening techniques are generally used by FSANZ only for food additives or potentially for novel foods. For contaminants, agricultural and veterinary chemicals and nutrients, experience has shown that a more refined modelling approach is usually required.

The method used for a dietary exposure assessment is clearly outlined in assessment reports prepared by FSANZ.

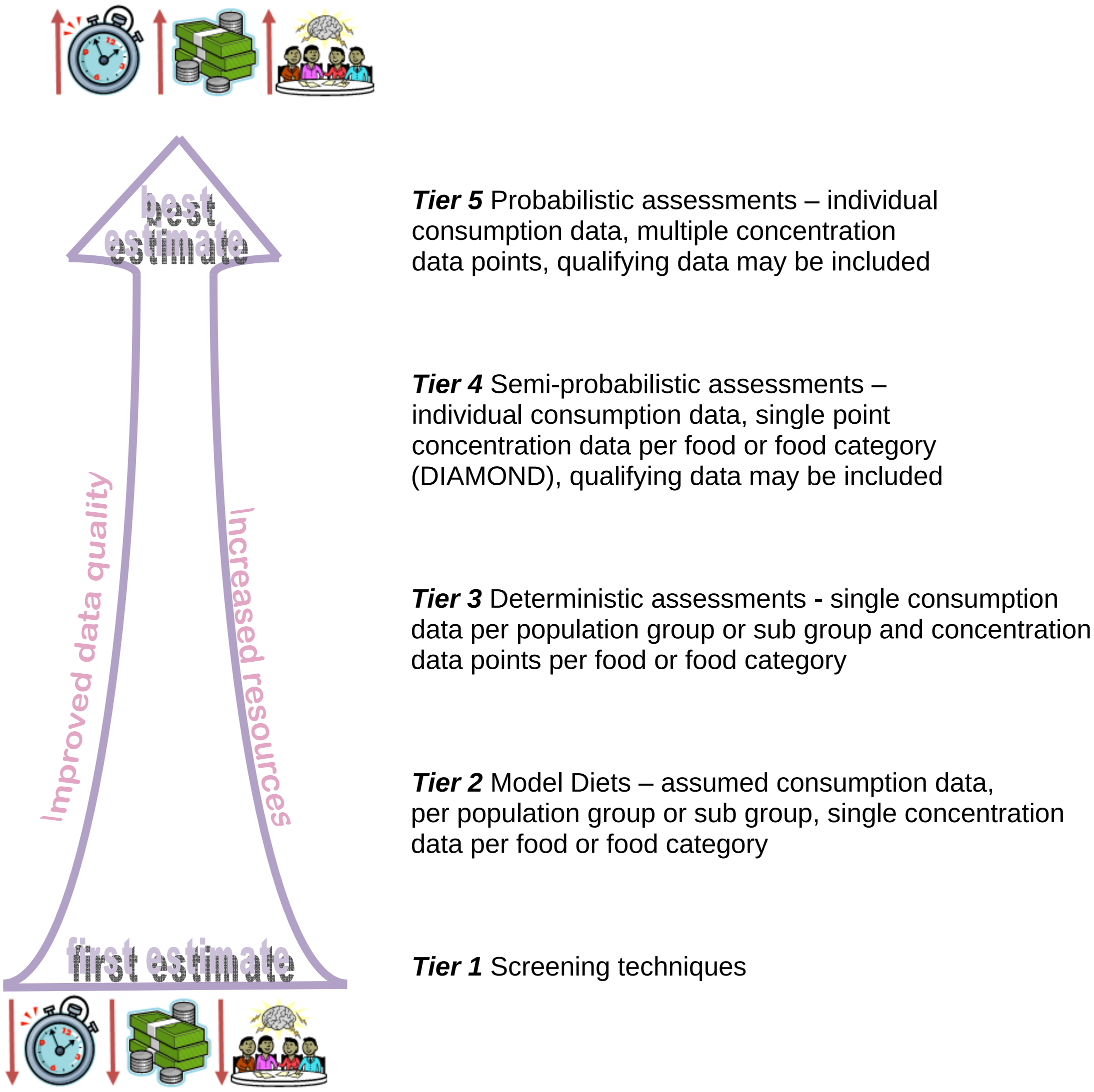

Figure 7. Schematic illustration of FSANZ's tiered approach to conducting dietary exposure assessments – as you move from a 'broad brush' first estimate to a targeted best estimate, data and resource requirements increase

4.2 Major techniques used in FSANZ dietary exposure assessments

There are many different ways a dietary exposure assessment can be conducted. Many of these outlined are described in more detail in the document *Project to update the principles and methods for the assessment of chemicals in food. Chapter 6 Dietary exposure assessment* (FAO/WHO, 2008). Methods used by FSANZ are outlined below, in approximate order of complexity.

4.2.1 Screening techniques

Screening techniques are quick and easy to use but generally are not sufficiently refined to allow detailed assessment of a hazard. They were used by FSANZ in the review of the Code that took place in the 1990s, as a tool for identifying those additives requiring a refined dietary exposure assessment. This 'priority setting' role of screening techniques remains one of their current main roles at FSANZ, for example in developing a risk matrix to allow rapid identification of foods that may present a significant risk (e.g. risks from a newly identified contaminant). Their other main use at FSANZ is to provide an early indication of whether permissions sought for a proposed new food additive are likely to exceed the relevant ADI.

Examples of calculations using screening techniques are found in Appendix 4.

Poundage data

With this technique, per capita availability of a food additive is estimated based on imports of an additive as well as any domestic production and can be adjusted to account for the fact that only a certain proportion of the population may consume the additive. The estimate is usually produced over a one year time period. There is considerable uncertainty associated with any exposure estimates based on these data as annual production or imports can vary markedly, non-food use is not accounted for, additive levels in imported foods cannot be assessed and individual exposure cannot be estimated. 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.

Budget method

The budget method is a screening technique developed in 1966 to estimate the levels of use of food additives that would result in dietary exposures being within safety limits (Hansen 1966, 1979, 1990). The method is used specifically for food additives (including processing aids and flavours) for which there is an ADI and does not require food consumption data for individuals. However it does not provide a dietary exposure estimate, cannot take high consumers of any particular food into account and provides very conservative ceilings of additive use.

The method sets a theoretical maximum level (expressed in mg/kg food), the primary ceiling, for use of an additive in all food and drink products. The ceilings or permissions for use are derived using the energy and fluid requirements of a 1-2 year old child, because this age group has the highest energy and fluid requirements per kilogram body weight, other than very young infants who do not consume solid foods. If the proposed additive concentration is below this primary ceiling, additional dietary exposure estimates may not be required.

A modified budget method can be used that takes into account the possible proportion of the food supply that could contain the additive, since it is unlikely that any additive will be used in all foods and beverages. The permitted level of additive for a restricted portion of the diet, the secondary ceiling, is then a multiple of the primary ceiling value.

The reverse budget method calculates the amount of food that it is necessary to consume in order for the ADI to be reached, assuming the maximum level of use, but can only be used for additives used in a few minor foods. An assessment is made as to whether consumption of this amount of food is likely or not, by reference to 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.

High consumer method

Food standards should protect those consumers who habitually eat large amounts of one or more particular foods or groups of foods (‘high consumers’). The high consumer method assesses the potential for a high consumer of specific foods or food groups containing the food chemical of interest to exceed reference health standards for a given food chemical. The method identifies the two representative foods which are likely to make the greatest contribution to total dietary exposure for that food chemical. The high food consumption amounts for these foods are multiplied by either maximum permitted levels of food chemicals or actual levels from survey data (EFSA, 2008).

The assumptions used in this high consumer model are based on work in the United Kingdom (Gregory et al, 1990) that indicates that the vast majority of people consume two or less foods at a high consumption level on any one day. 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 or three foods could be consumed in large quantities, therefore making the high consumer model invalid.

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 reference health standard. The calculation can take into account contributions to total dietary exposure from all other foods consumed at a population average level. TMALs can be calculated for all food chemicals, but are mainly used for contaminants.

The TMAL is generally calculated using a high consumption amount (for example the 95^{th} percentile) for the commodity or food group of interest. 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. 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 health standard.

A method described as a ‘back calculation’ is similar to the TMAL, however focussing on a different part of the dietary exposure assessment equation. This method is generally used to assist in making risk management decisions on the amount of a food that can be consumed before the reference health standard is exceeded, based on a known concentration of a chemical in the food. 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 (http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2004/mercuryinfishfurther2394.cfm).

4.2.2 Model diet techniques

Where no food consumption data for individuals exists from national food consumption surveys, model diets can be constructed. FSANZ generally only uses model diets when assessing dietary exposure in infants, as NNS data do not cover children under the age of 2 years (for Australia) or 5 years (New Zealand). At times, however, FSANZ may use simple model diets for assessment of food chemicals that are present in a very narrow range of foods. More detail on model diets as used by FSANZ is provided in section 3.2.2.

4.2.3 Individual dietary records approach

Dietary exposure assessments using food consumption data for individuals may be necessary if the results of exposure assessments, using screening methods or model diets, are not conclusive or indicate that potential dietary exposure to a food chemical is likely to approach or exceed reference health standards. Alternatively, they may be used in the first instance if the data are available and an accurate estimate of dietary exposure is likely to be required. The usual dietary modelling 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 agricultural and veterinary chemicals, or can be incorporated into our customised data management system, DIAMOND, using a semi-probabilistic approach.

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.

Individual dietary records approach – deterministic technique

In deterministic, or point-estimate assessments, 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. The estimated dietary exposure may then be divided by a single body weight to obtain an estimate of dietary exposure for comparison with the relevant health standard. Deterministic assessments are straightforward to conduct and the outputs are relatively simple to understand. They do not provide information on the likelihood of the estimated level of dietary exposure occurring. The single data points used in the deterministic assessments are generally means for the population group being assessed, but sometimes medians or high percentile values depending on the purpose of the dietary exposure assessment

The food consumption amounts are derived from individual NNS consumption amounts, such as the mean or 95th percentile consumption of all survey respondents or of a particular sub-group. When conducting a standard deterministic calculation for a chemical in many foods, 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 agricultural and veterinary chemicals. These are outlined in section 5.4.

Individual dietary records approach – semi-probabilistic technique

The most common technique FSANZ uses in dietary exposure assessment is to match individual food consumption data with a single point chemical concentration per food or food group, to generate a range of individual dietary exposures. FSANZ terms this technique 'semi probabilistic', and it is conducted using FSANZ's dietary modelling program DIAMOND (Appendix 1 outlines the operation of the DIAMOND program). The individual consumption data generally come from NNSs based on 24-hour recall. Other data sources may include one-day diary records.

When individual records of food consumption are used, information can be generated on the distribution of food chemical dietary exposures in the population in addition to data on mean, median or percentile exposures for all respondents or 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 food range, a special survey or assessment may be more accurate. FSANZ has used this approach to investigate dietary exposure to intense sweeteners (FSANZ, 2004a). In this case, a seven day diary of consumption of intense sweetened foods was completed by frequent users of these foods and the individuals' diary consumption data, rather than NNS consumption data, were used to predict sweetener exposure. This was a resource intensive project, in particular in relation to the time taken to collate a brand- and flavour-specific database of the sweetener content of all foods available in Australia and New Zealand containing intense sweeteners, and would generally not be warranted for most assessments.

Probabilistic 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. 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 also estimates the probability of a population exceeding a given reference health standard (Boon et al 2003). Probabilistic modelling can also more readily take account of variations in factors such as daily food consumption, food chemical concentrations, purchasing behaviours and body weights across a population or population sub-group (FAO/WHO, 2008).

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 (typically between 5,000 and 10 000 times) to generate a distribution of potential exposures. This 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 Codex Committee on Pesticide Residues (CCPR) actively pursuing this technique for acute dietary exposure assessments of pesticide residues. There are a number of commercial probabilistic modelling software packages available including @Risk, the Monte Carlo Risk Assessment (MCRA) software, Crystal Ball and Analytica. Other agencies internationally have developed their own customised probabilistic computer programs specifically for estimating dietary exposure. The FAO/WHO (2008) has recently produced a summary of probabilistic modelling for dietary exposure purposes.

FSANZ has used probabilistic techniques in modelling associated with the risk assessment of microbiological hazards but is still investigating their application to dietary exposure assessment of food chemicals. However, the @Risk program has been used by FSANZ to assess acute dietary exposure to hydrocyanic acid in packaged salty snacks (see figure 8). Future uses of this technique may include assessment of chronic exposure of consumers regularly exposed to high contaminant levels and potentially to assess population exposure to allergens (Spanjersberg et al, 2007).

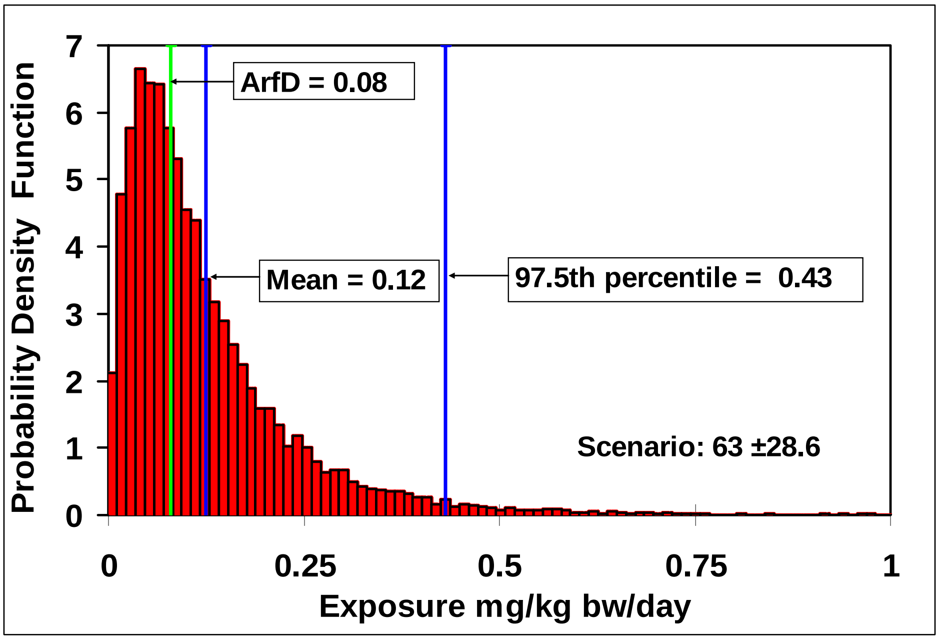

Figure 8: Distribution of exposure (mg/kg body weight/day) to hydrocyanic acid from cassava chips of Australian 2-4 year olds at a HCN concentration of 63±28.6 mg/kg

4.2.4 Cumulative 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. The need to undertake a cumulative assessment will depend on the findings of the hazard characterisation step in the risk assessment process. FSANZ has undertaken a cumulative assessment for dioxins that took into account the levels and toxic equivalence factor (TEF) of 29 dioxin congeners (FSANZ, 2004b).

4.2.5 Exposure estimates including sources other than the diet

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, supplements, cosmetics etc. Aggregate exposure assessments recognise that exposure to food chemicals may arise from the use of the same chemicals in non-food contexts. Consideration of combined exposures to a single chemical across multiple routes (oral, dermal, inhalation) and across multiple pathways (food, drinking-water, residential) is known as "aggregate exposure".

At FSANZ, aggregate exposure assessments are not routinely conducted, other than to include information on possible oral exposure through the use of ingested medicines. A recent case where aggregate exposure has been taken into account, semi-quantitatively, was the assessment of total fluoride intakes from food, drinking water and toothpaste as part of Application 588 Voluntary addition of fluoride to packaged water (see http://www.foodstandards.gov.au/standards development).

4.3 Age groups assessed

Ideally, dietary exposure assessments should cover the whole population and should also include relevant population sub-groups, such as young children, 'at risk' or target groups. Wherever possible, FSANZ will account for these sub-groups in both Australia and New Zealand in exposure assessments. Chapter 5 of this document identifies the sub-groups routinely reported in exposure assessments for different types of food chemicals.

Regardless of the method of dietary exposure assessment used, dietary exposure of young children to the food chemical in question will generally 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 and therefore they eat more food in relation to their size than adults do. This is particularly so for very young children. Children also consume more drinking water than adults, on a body weight basis (Buck Louis et al., 2006). Total food and water consumption is often highest at adolescence as children grow very rapidly at this time (Buck Louis et al., 2006). This will be particularly true of adolescent boys whose exposure may be assessed separately where this is relevant.

Children may have unusual eating patterns, ranging from picky and irregular eating, overeating, to disinhibited or binge eating (Lewinsohn *et al* 2005, Marcus and Kalarchian 2003), that may be particularly relevant when assessing 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 (Buck Louis et al., 2006).

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.

4.4 Duration of exposure – acute or chronic assessments

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 chronic dietary exposure assessment techniques are used to assess long 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 chronic assessments, the exact nature of the hazard being assessed determines the final dietary modelling approach on a case-by-case basis.

4.4.1 Acute dietary exposure assessments

Acute dietary exposure assessments are conducted for food chemicals that have toxic effects from short-term exposure (from one meal or over one day). A Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals in 1997 (FAO/WHO, 1997b) developed a methodology for performing short term (acute) dietary exposure assessments. This methodology, although developed and discussed in the context of agricultural and veterinary 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 assessments for other chemicals, such as sugar alcohols, that may induce gastrointestinal effects after single large doses, but for which an acute reference dose 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) is multiplied by a high chemical concentration amount, where a distribution of chemical concentrations is known. 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 section 5.4.2).

FSANZ 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 generated over a 24-hour period and any food eaten over one day could potentially be eaten on a single occasion. Because exposure over a short time period is being assessed, the statistical adjustments that may be undertaken for chronic dietary exposure assessments (see section 4.5) are not appropriate.

Although acute 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. However it would 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.

FSANZ has begun to use probabilistic modelling techniques to assess acute exposure to food chemicals (for example, see figure 8). 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.

4.4.2 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. 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. 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. 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.

4.5 Using 24-hour recall data to predict long term consumption

Most of the national nutrition surveys used by FSANZ collected a single 24-hour recall on all respondents. 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.

Mean daily food consumption amounts estimated from survey data may decline as the length of a survey increases (see figure 9), depending on the type of food consumed. For frequently consumed foods, the mean amount of food consumed per day, calculated from 1, 2, 7 or 14 day data, may not change significantly (IEFS, 1998; Council, Verger & Voilatier, 2006); for example, we may continue to eat two slices of bread or a 200 ml glass of milk every day. However, the daily mean consumption of occasionally consumed foods will decrease if more than one day of data is considered; figure 9 clearly shows this for pizza.

The distribution of food consumption amounts for a survey of one 24-hour duration is much broader than that of two or more days. Therefore, the number of days of food consumption data affects the predicted high food consumption amount, which in turn affects estimated high consumer dietary exposure, particularly for food chemicals in occasionally consumed foods. Figure 10 shows, for sausages, how the use of one day of consumption data exaggerates high consumption amounts. The data in figure 10 are taken from the subset of 1995 Australian NNS participants who completed a second day of the survey and ate sausages on both survey days. In this example, the 95th percentile of sausage consumption based on one day of data was 12% above the 95th percentile of consumption assessed over two days, and 60% above at the 99th percentile.

Because of the exaggeration of extremes of consumption that arises from use of a single day's consumption data, FSANZ has adopted a policy that a high consumer's chronic dietary exposure is best represented by the 90th percentile of exposure, where estimates of dietary exposure are based on food consumption data from a single 24-hour recall from NNSs. This replaces the previous standard use of the 95th percentile and is in line with international best practice.

Other percentiles are used to represent the high consumer for nutrient intake assessments (see section 4.5.1) and for acute exposure assessments of agricultural and veterinary chemical residues. In some circumstances risk assessors and/or risk managers at FSANZ may choose to use other reporting cut-off 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.

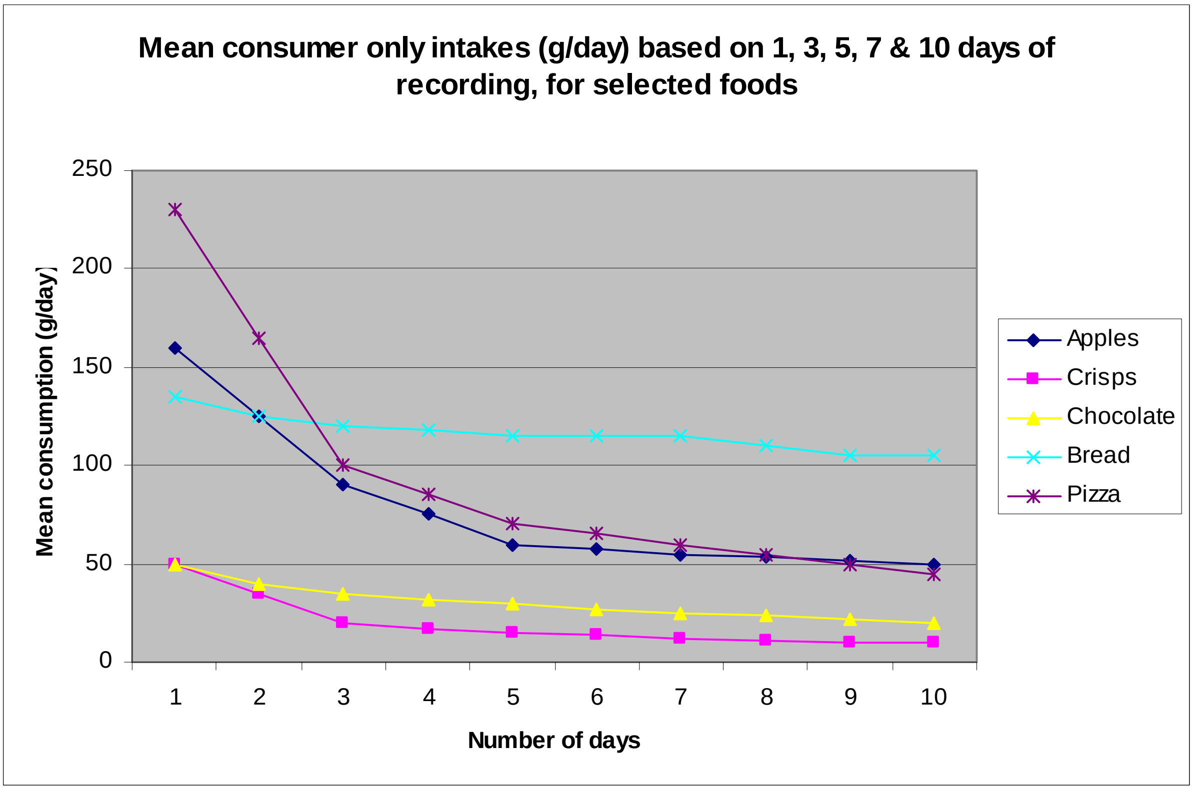

Figure 9: Effect of survey duration on estimate of daily amount of food consumed (adapted from IEFS, 1998)

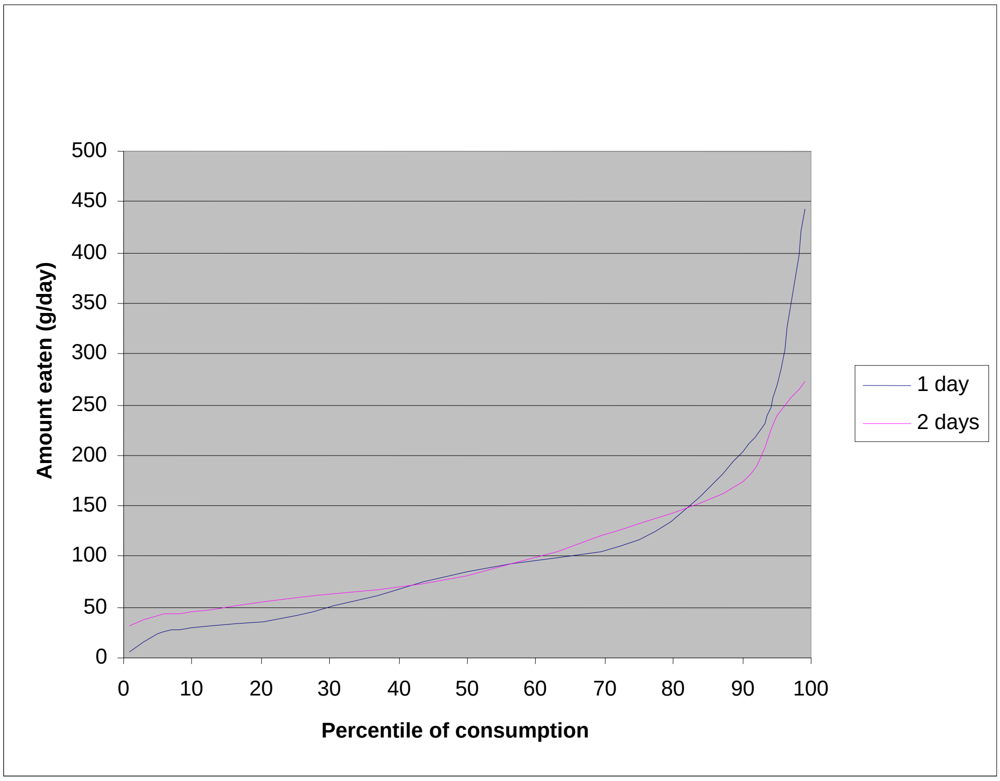

Figure 10: Effect of survey duration (one or two days) on estimates of daily amount of sausages consumed (adapted from NNS 1995 using DIAMOND)

The 2007 Australian children's NNS, in contrast to the other NNSs used by FSANZ, included a second 24-hour recall for all respondents, conducted on a non-consecutive day. When reporting food consumption or chronic dietary exposure using this survey, FSANZ will average consumption or exposure over two days and continue to use the 95th percentile as the most appropriate representation of the high consumer. However FSANZ will investigate the use of this survey in more detail as time permits and may in future reach a different view about the best way to represent the high consumer using this survey.

4.5.1 Second day adjusted nutrient intake

For nutrients, two days of food consumption data for a subset of NNS respondents are used to estimate 'usual' nutrient intake in all NNS respondents, where the intakes are normally distributed. This method uses established statistical adjustments. This adjustment process is appropriate to use for nutrients, 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. A 10% (1995 Australian NNS) or 15% (1997 and 2002 New Zealand NNSs) sub-sample for which two 24-hour recalls are available is generally sufficient to allow estimation of the within-person standard deviation for nutrients.

DIAMOND is able to calculate adjustment factors for specific age groups and specific nutrients and apply these factors 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 in the formula described in figure 11 below. This is the same technique that was used by the Australian Bureau of Statistics (ABS) to produce the nutrient intake estimates published in the 1995 NNS (Rutishauser, 2000).

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

Where:
- x is the group mean nutrient intake for the 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

Figure 11: Calculating adjusted nutrient intakes (Source: Rutishauser, 2000)

A minimum number (100) of respondents in the second day are needed to generate a statistically valid adjustment factor. FSANZ uses 'collapsed' age groups (2-13 years, 14-34 or 15-34 years and 34 years and above) to ensure there are sufficient second day respondents. However DIAMOND compares each individual's adjusted intake with the NRV for their actual age and gender.

Figure 12 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 adjusted nutrient intakes will not be significantly different from unadjusted mean intakes. However the 95th percentile intake will be lower than the unadjusted 95th percentile intake and the 5th percentile intake will be higher than the unadjusted 5th percentile intake.

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. For these nutrients, an intake assessment on single 24-hour recall data will be conducted and the 90th percentile used to represent the high consumer, with the 10th percentile to represent the low consumer.

Percent contributions of foods or food groups to overall nutrient intake are generally reported in FSANZ dietary exposure assessments. For nutrient intake assessments these 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 continue 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.

FSANZ is still investigating the most appropriate way to estimate longer term nutrient intake using the 2007 Australian NNS where two days of intake data are available for each respondent. The same approach as outlined above could be used, drawing on each individual's day 1 intake adjusted using the day 2 intakes of a randomly selected subset of respondents. Alternatively, each individual's day 1 and day 2 intakes could be averaged and no further statistical adjustments applied.

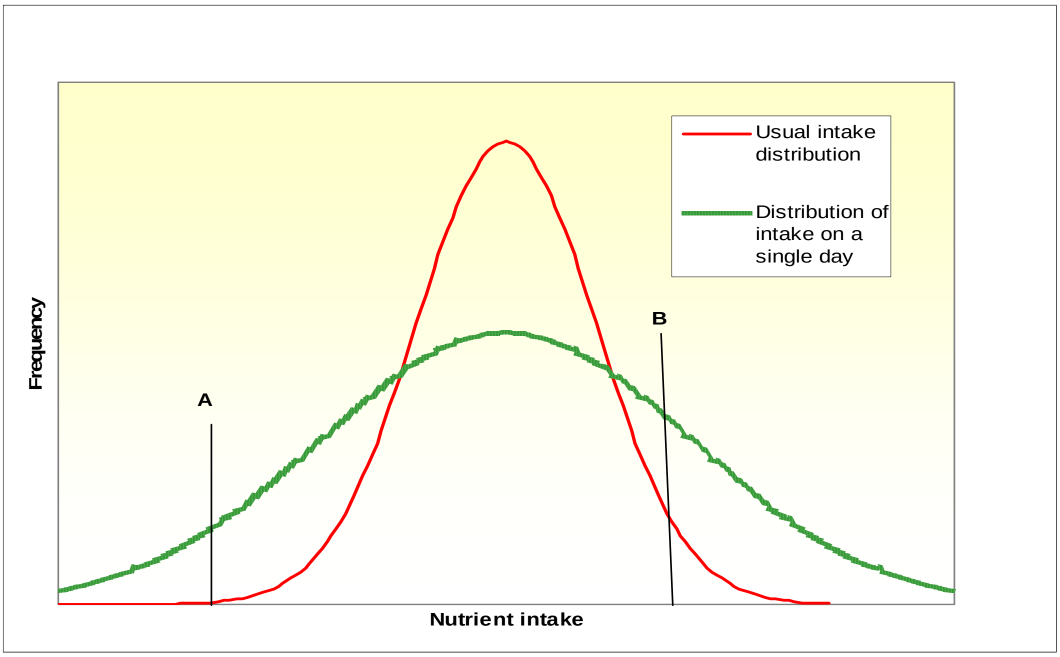

Figure 12: Comparison of one day and usual intake distributions of nutrient intakes. Points A and B represent NRVs for adequacy (A) and excess (B)

4.5.2 Second day adjustment of food consumption data

It is not appropriate to use the same statistical adjustment process that is used for nutrients for other food chemicals or for food consumption amounts. Food consumption is highly variable from day to day and a 10% or 15% 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 adjustment to be applied.

4.6 Market weighted assessment

Applicants for new food additives or novel foods may provide advice 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. FSANZ terms this approach a 'market weighted' assessment and it provides information on the population average or high exposure to an additive assuming that consumers chose from a range of products, of potentially varying formulation, over their lifetime.

FSANZ does not alter the NNS food consumption data (adding or deleting foods or altering amounts eaten) in DIAMOND. Therefore in order to integrate this market share information into the quantitative, semi-probabilistic assessments produced by DIAMOND, FSANZ alters the food chemical concentration assigned to a food group in proportion to the anticipated market share. 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. 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, and will underestimate exposure for those who deliberately consume a food containing the chemical and it will overestimate exposure for people who avoid the chemical.

In the absence of information on market share, FSANZ may estimate 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 agricultural and veterinary chemicals, the proportion of a commodity actually treated with a pesticide can be taken into account. However this information is not commonly available and therefore a market share approach is generally not used for this class of food chemical. In an acute dietary exposure assessment, market share data can be used to represent the size of a population potentially exposed to the risk.

4.7 Consumer behaviour assessment

A consumer behaviour assessment examines the scenario where consumers deliberately choose, or deliberately avoid, foods containing the food chemical. This can be the case for foods voluntarily fortified with a particular nutrient. In the case of a food additive, this 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 food chemical in that brand. A consumer behaviour assessment is usually used where the chemical is deliberately added to specific foods and therefore consumers are able to exercise choice regarding consumption based on label information. It is less relevant for contaminants and pesticides 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 where consumers may be sourcing foods from a limited geographical location subject to a different contamination pattern. Figure 13 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).

4.8 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’. 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 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 reference health standard. This helps to establish where a higher MPL could be set and still protect public health and safety.

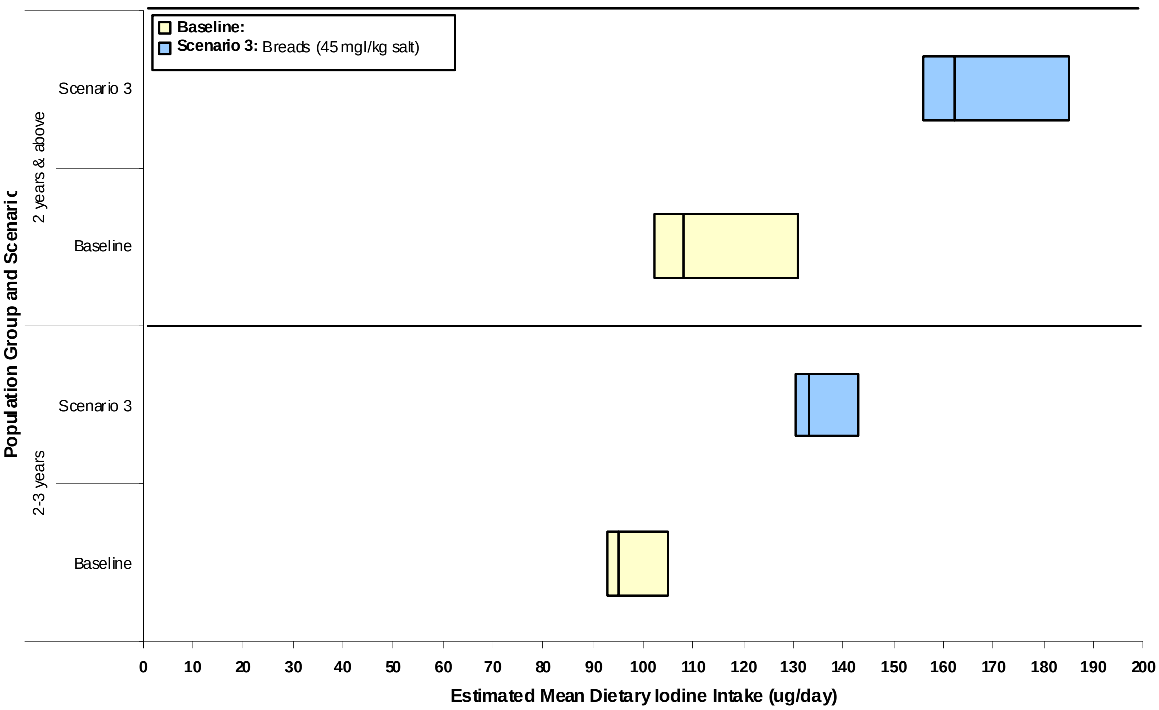

Figure 13. The effect of using a consumer behaviour model (boxes) compared to a market share model (single black line within the boxes) on estimates of total iodine intake before and after fortification with iodine of salt used in breadmaking. The boxes show the range in iodine intake possible if you assume consumers never choose iodised salt or always choose iodised salt, in cooking and at the table.

4.9 Conventions on reporting

A large number of data points are typically produced as part of a dietary exposure assessment done using DIAMOND. Only some of these results, those that are central to an issue under investigation, will be presented in an assessment report. Other results will 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 risk assessment questions that need to be addressed. In general:

- Separate results will be presented for Australia and New Zealand.
- For New Zealand, results for Maori and Pacific people may be reported separately to results for New Zealanders of European and Other origin (NZEO).
- Results for the full survey population will be presented and usually also for young children. Other age groups, vulnerable groups or target groups may be assessed if relevant.
- Results will be expressed on the same basis as the reference health standard 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 or in tables, but will generally not be presented in both formats within the body of a report. Detailed information is generally provided within attachments to a report.

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 decimal places, 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 exposure as a percentage of a reference health standard, exposure less than 10% of the standard will be reported to the nearest whole number (e.g. 9%), between 10 and 100% of the standard will be reported to the nearest 5% (e.g. 43% becomes 45%), and over 100% of the reference health standard will be reported to the nearest 10% (e.g. 107% becomes 110%).

5. ASSESSING DIFFERENT FOOD CHEMICAL CLASSES

In this chapter, dietary modelling techniques are outlined for the major categories of food chemicals that FSANZ assesses – food additives (including processing aids), contaminants, agricultural and veterinary chemicals, novel foods and ingredients, and nutrients. Brief information is also provided on techniques that can be used to model exposure to packaging contaminants and flavours, although FSANZ does not at present conduct such assessments.

5.1 General approach

There are many different considerations that need to be made before starting a dietary exposure assessment. Figure 14 sets out the general steps that FSANZ follows in conducting a dietary exposure assessment. While there are general approaches for each class of chemical (see table 4), the assessment of each individual chemical is conducted on a case by case basis. Table 5 sets out the usual reporting conventions for different classes of food chemical. More specific details are explained further below in sections 5.2 to 5.8.

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 FAO/WHO in conjunction with the appropriate Codex committees (FAO/WHO, 2008; UNEP/FAO/WHO, 1989; UNEP/FAO/WHO, 1992; FAO/WHO, 1995b). FSANZ follows these where applicable.

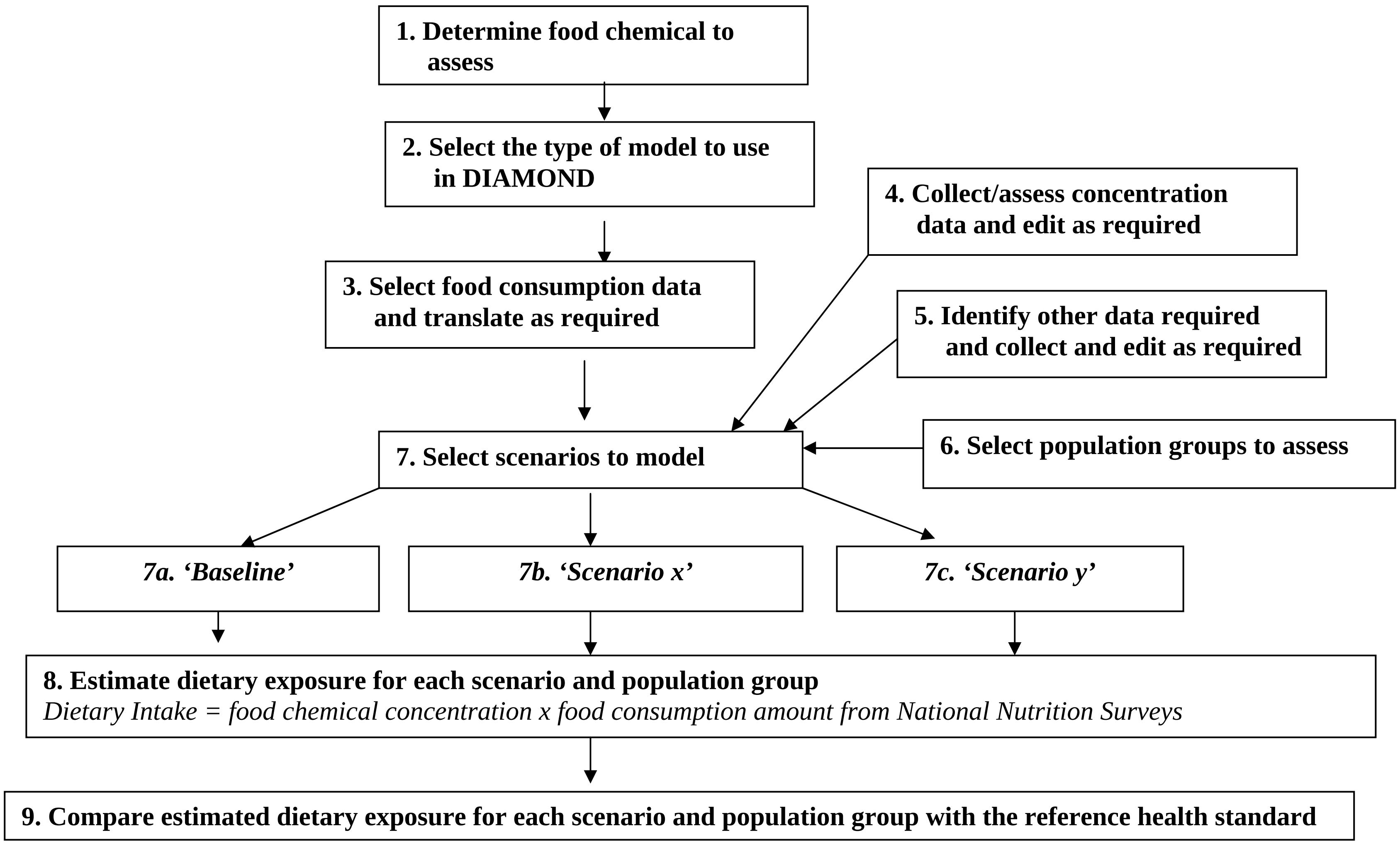

Figure 14. An example of the steps in undertaking a dietary exposure assessment using DIAMOND

Table 4: Information that could be used for conducting dietary exposure assessments for different classes of food chemicals*

	FOOD CHEMICAL					
	Food Additive	**Contaminant**	**Pesticide**	**Nutrient**	**Ingredient**	**Novel Food/ Ingredients**
Consumption Data	Raw and Processed Commodities	Raw Commodities	Raw Commodities	Raw and Processed Commodities	Raw and Processed Commodities	Raw and Processed Commodities
Concentration Data	Maximum Permitted Levels (MPL) from food standards. Manufacturers' use level. Analytical survey data.	Maximum Levels (ML) from food standards. Survey data (e.g. surveillance and total diet surveys).	Maximum Residue Limits (MRL) from food standards. Trial data. Analytical survey data (e.g. ATDS) Processing Factors.	Food composition tables. Maximum permitted or claimable levels from food standards. Analytical data. Proposed nutrient fortification levels.	Maximum Permitted Levels (MPL) from food standards. Manufacturer use levels. Analytical/survey data. Proposed levels of use.	Maximum Permitted Levels (MPL) from food standards. Manufacturer use levels. Analytical/survey data. Proposed levels of use.
Reference Health Standards (Standard chosen depends on the nature of the assessment)	Acceptable Daily Intake (ADI) Acute Reference Dose (ARfD) if set	Provisional Tolerable Daily (PTDI), Weekly (PTWI) or Monthly (PTMI) Intake Benchmark dose (BMD) Acute Reference Dose (ARfD) if set	Acceptable Daily Intake (ADI) Acute Reference Dose (ARfD)	Estimated Average Requirement (EAR) Recommended Dietary Intake (RDI) Upper Level (UL) Adequate Intake (AI) Suggested Dietary Target (SDT) or Acceptable Macronutrient Distribution Range (AMDR)	Adverse effect level or as advised by FSANZ toxicologists.	Adverse effect level or as advised by FSANZ toxicologists. Acceptable Daily Intake (ADI) and/or Acute Reference Dose (ARfD) if set
Duration of exposure	Chronic Occasionally acute	Chronic Occasionally acute	Acute and chronic	Mainly chronic Occasionally acute	Mainly chronic Occasionally acute	Acute and chronic

* 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 5: Reporting conventions for FSANZ dietary exposure assessments for different classes of food chemicals

	FOOD CHEMICAL					
	Food Additive	**Contaminant**	**Agricultural & veterinary chemical – chronic exposure**	**Agricultural & veterinary chemical – acute exposure**	**Novel food or ingredient**	**Nutrient**
Population groups reported (general guide only; additional groups may be assessed depending on the specific risk assessment)*	Australia: 2-6 years 6-16 years 17+ years New Zealand: 5-14 years 15+ years Infants 0-12 months (depending on assessment)	Australia: 2-6 years 6-16 years 17+ years New Zealand: 5-14 years 15+ years Both countries: Females 15-44 years (depends on assessment) Infants 0-12 months (depending on assessment)	Australia only: 2+ years (1995 NNS data used only)	Australia only: 2-6 years 2+ years 1995 NNS data used only In some circumstances, may include 2-6 years, 2007 NNS	Australia: 2-6 years 6-16 years 17+ years New Zealand: 5-14 years 15+ years Infants 0-12 months (depending on assessment)	NRV age and gender groups for the nutrient being assessed
Adjustment for longer term consumption?	Generally no. Two day average consumption and/or exposure may be reported for Australian children (2-16 years)	Generally no. Two day average consumption and/or exposure may be reported for Australian children (2-16 years)	No	No	Generally no. Two day average consumption and/or exposure may be reported for Australian children (2-16 years)	Yes

FOOD CHEMICAL						
	Food Additive	**Contaminant**	**Agricultural & veterinary chemical – chronic exposure**	**Agricultural & veterinary chemical – acute exposure**	**Novel food or ingredient**	**Nutrient**
Statistics reported	Mean respondent and consumer exposure 90th percentile consumer exposure (95th percentile if using 2007 Australian NNS) Exposure reported on bodyweight basis and as % ADI/ARfD % contribution to exposure of different food groups % population >ADI	Mean respondent and consumer exposure 90th percentile consumer exposure (95th percentile if using 2007 Australian NNS) Exposure on a bodyweight basis and as % PTI /ARfD % contribution to exposure of different food groups	National Estimated Dietary Intake (NEDI) (bodyweight basis) NEDI reported as a percentage of the ADI.	National Estimated Short Term Intake (NESTI) (bodyweight basis) NESTI reported as a percentage of the ARfD	Mean respondent and consumer exposure 90th percentile consumer exposure (95th percentile if using 2007 Australian NNS) Basis of reporting (total, bodyweight, % of reference health standard) will depend on information available and assessment needs	Mean respondent exposure 5th and 95th percentile respondent exposure % of respondents under the EAR (where available) % of respondents over the UL (where available). % contribution to intake of different food groups
Market weighted and/or consumer behaviour	Likely	No	Unlikely	No	Likely	Likely

* Somewhat different age groups reported for Australian children compared to New Zealand children reflects the differing age groups selected in the 2007 vs 2002 national children's nutrition surveys; for agricultural and veterinary chemicals, the 1995 NNS data are used for the whole population assessment

5.2 Food additives

The procedures used at FSANZ to assess the risks of food additive use are consistent with guidelines published by JECFA (FAO/WHO, 1989).

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.
- Dietary exposure can be estimated using maximum permitted levels (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 exposure is needed.
- A dietary exposure assessment is not normally conducted to assess issues such as allergic or intolerance reactions.

The FAO/WHO guidelines outline two ways of expressing food additive intake: theoretical maximum daily intake (TMDI) which is based on MPLs (established in the Code or being sought by applicants), and estimated daily intake (EDI) based on actual use levels. Initially, TMDI calculations may be undertaken as a screening technique. Information on the screening techniques used at FSANZ is provided in section 4.2.1.

Past experience at FSANZ has shown that screening techniques are generally insufficient to assess a new food additive. However they can be very useful to illustrate in a simple manner the magnitude of potential exceedance of the reference health standard and therefore provide early guidance to risk managers of the need to amend an application or proposal.

5.2.1 Food additive dietary exposure estimates using DIAMOND

Food additive concentration data used

In the first instance, a dietary exposure assessment for a food additive will use the proposed use level identified by the applicant, together with MPLs for any existing uses of the additive. The proposed 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 overestimate in concentration are less than the ADI.

If initial exposure 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 share estimates, or narrowing of the food group to more specific product types (e.g. apple juice instead of all types of fruit juice), will be undertaken. Actual use levels for foods with existing additive permissions could be used.

In submitting data to JECFA or similar international group, FSANZ will use MPLs set out in the Codex General Standard on Food Additives (GSFA), matched with Australian or New

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

Food consumption data used

DIAMOND food additive groupings will be used to select the relevant consumed foods from NNSs. For example, if an additive is proposed for use in skim milk powder (category *1.5 Dried milk, milk powder, cream powder)*, all foods consumed that have been translated to that food category will be assumed to contain the additive at the proposed use 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 DIAMOND has been set up.

Should the initial exposure estimate indicate exposure above the reference health standard, the proposed use level would then be assigned to the specific food for which permission is sought (in this example, *Skim milk powder)*.

Where relevant, exposure through non-food use of an additive (e.g. from medicines 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.

Reporting of exposure estimates

Table 5 identifies the usual conventions for reporting dietary exposure to food additives. Where a reference health standard 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 reference health standard, 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. Where an additive is not likely to be one specifically sought out by consumers, a consumer behaviour assessment is not relevant.

Under some circumstances, the percentage contribution to exposure from different food groups will be reported, where this is helpful to understanding the dietary exposure assessment. DIAMOND has the facility to identify individual consumers from NNSs whose calculated additive intakes exceed the reference health standard. From records of their food consumption, it may be possible to assess if there are specific foods that are likely to cause excessive additive intakes. This may be useful by identifying those foods that could be particular targets of risk management measures.

5.3 Contaminants

The general considerations for dietary exposure assessments for contaminants 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.
- Dietary exposure is generally assessed using concentrations from survey data rather than Maximum levels (MLs).
- On occasion, some contaminants 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 at FSANZ to assess the risk of food contamination are consistent with guidelines recommended by Codex (UNEP/FAO/WHO, 1992).

5.3.1 Contaminant dietary exposure assessments using DIAMOND

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

One of the difficulties of estimating contaminant 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). DIAMOND contains recipe information that can be used to disaggregate NNS consumption data for processed foods to the equivalent unprocessed commodities.

Contaminant concentration data – sources and uses

The Report of the 27th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) (CCFAC, 1995) 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 the average and for high consumers".

In the first instance, a dietary exposure assessment for a contaminant could use the maximum level (ML) set out in the Code, if such levels are established. However MLs will not be established for foods that are minor contributors to dietary exposure and therefore use of MLs alone will potentially underestimate dietary exposure to the contaminant unless some allowance is made for these minor contributors. Where MLs are set they are generally higher than actual contaminant concentrations. Guideline levels, such as Generally Expected Levels (GELs), or levels set by WHO or bodies such as the NHMRC can also be used in the dietary exposure assessments.

For newly-identified contaminants (e.g. melamine), 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 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), 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 and pesticide residue data are available from the WHO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food) for selected commodities important to international trade. The amount of data available on contaminants varies considerably and for most commodities the contaminant data set is not extensive, particularly where a contaminant is newly identified. Certain commodities that are known contributors of contaminants are often targeted for analyses, for example fish, seafood and offal.

Contaminant concentration distribution curves are often positively skewed, with mean values higher than medians due to a small proportion of high concentrations. In these cases, the median value may be used in dietary models.

Analytical surveys will often report levels of a contaminant as being below the LOQ. Depending on the nature of the contaminant, 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.

Food consumption data used

DIAMOND raw commodity groupings will be used to select the relevant consumed foods from NNSs.

Exposure to some contaminants 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.

Reporting of exposure

Table 5 sets out the usual conventions for reporting the results of a chronic dietary exposure assessment for contaminants. Where a contaminant is part of a group of contaminants for which there is a group reference health standard, exposure assessments will take the potential contaminant intake from the whole group into account. For contaminants without a reference health standard, such as a carcinogen, total exposure will be reported as well as the margin of exposure.

Dietary exposure of females of reproductive age is often reported separately as some contaminants may pose a particular risk to the developing fetus. Very young children are commonly assessed separately to pre-school age 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 may be more important for very young children.

Consumer behaviour assessments are generally not relevant to the assessment of contaminants dietary exposure as consumers would not be expected to intentionally select or avoid foods containing a contaminant.

The percentage contribution to 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 (CAC, 2007). DIAMOND has the facility to identify individual consumers from NNSs whose estimated contaminant exposure exceeds the reference health standard. From records of their food consumption, 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, 97.5th percentile consumer exposure is generally reported. Very young children are generally the focus of an acute exposure assessment for a contaminant because of the typically higher exposure of very young children to food chemicals, when expressed on a bodyweight basis.

5.4 Agricultural and veterinary chemicals

The majority of dietary exposure assessments that FSANZ performs for agricultural and veterinary chemicals are conducted in conjunction with the Australian Pesticides and Veterinary Medicines Authority (APVMA), under an established protocol. On occasion, FSANZ may assess exposure to an agricultural and veterinary chemical found in imported foods, for which APVMA does not have a role. The dietary exposure assessment techniques will be the same in both cases and align with international conventions.

The general considerations for dietary exposure assessments for agricultural and veterinary chemicals are as follows:

- These chemicals are specifically added to foods and therefore are usually in a restricted range of raw commodities and processed foods and beverages.
- They are assessed using concentrations from standards (MRLs), trial data or analytical survey data.
- FSANZ assesses agricultural and veterinary chemicals for Australia only as Standard 1.4.2 applies in Australia only.

The exposure assessment may be a chronic assessment only or may be both a chronic and acute assessment, depending on the properties of the chemical in question. Generally a deterministic approach is used to estimate dietary exposure to agricultural and veterinary chemicals, except where the FSANZ dietary exposure assessment computer program, DIAMOND is used.

5.4.1 Dietary exposure methodologies – chronic assessments

Agricultural and veterinary chemical concentration data used

In most 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. Trial residue data refer to the raw commodity 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 provided than if MRLs are used. Processing factors may be applied where relevant to take account of loss of, or concentration of, agricultural and veterinary chemicals from raw commodities as they are transported, stored, processed and prepared.

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

Whether an MRL or STMR is used in an assessment, it will generally be assumed that the chemical in question is applied to all foods 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 an initial dietary exposure assessment.

At times FSANZ may also draw on other agricultural and veterinary chemical 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 (DAFF). The NRS provides extensive data for agricultural and veterinary 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.

Where analytical survey data are used, mean chemical concentrations for each food are usually derived for use in the dietary exposure assessment. Where 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 concentration means the chemical was not actually applied to that food.

The WHO collates member country concentration data on selected agricultural chemical and veterinary drug residues important to commodities in international trade. 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.

Use of Australian Total Diet Study (ATDS) data

ATDS concentration data and dietary exposure estimates may be available for many agricultural and veterinary chemicals for which dietary exposure assessments are being conducted. The ATDS data generally give a more accurate estimate of longer term dietary exposure because they will incorporate a proportion of commodities that are not treated with a given chemical. In many cases, the ATDS is the only information on the level of residues in foods as consumed, because foods are analysed as consumed rather than as raw commodities. ATDS results are an estimate of the agricultural and veterinary chemical residue dietary exposures for Australians in the survey year and can provide confirmation that established agricultural chemical controls for practical commercial conditions in Australia are resulting in safe dietary exposures. 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 agricultural chemical uses will have a public health impact or not.

Where ATDS dietary exposure assessments are available for a given agricultural or veterinary chemical, these results will generally be presented together with the dietary exposure estimate prepared using agreed procedures, as an estimate of the more likely, or realistic, exposure.

Reduction/concentration factors

The levels of agricultural and veterinary chemical residues in foods are usually reported on commodities of trade, and adjustments are necessary to predict the content in the edible portion of the food or in mixed foods. Reduction or concentration 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.

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) (WHO, 2008). 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 agricultural and veterinary chemical residues that are fat soluble, the differences in distribution of a specific residue in the meat 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 a certain percentage of fat for each commodity, for example, 10% fat in meat and 5% fat in milk (as a worst case scenario) and 100% in the fat, unless known otherwise.

Food consumption data

For the purposes of the deterministic assessments conducted for agricultural and veterinary chemicals, FSANZ has developed data tables that report mean consumption for all respondents in the 1995 Australian NNS for specific raw commodities for the whole population 2 years of age and above, to represent lifetime consumption of these commodities.

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 NNS, a default consumption figure (0.0001 g/kg bw/day) is used as an estimate of mean population consumption for the purposes of dietary exposure assessment.

Dietary modelling technique used

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. Any one chronic dietary exposure calculation may contain a combination of these but the NEDI is the approach most commonly used by FSANZ and APVMA.

The NEDI can be defined as:

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

where F_i is the average amount of the commodity reported as consumed by the whole population and STMR-P_i is the supervised trial median residue level of the corresponding food commodity, incorporating processing/edible portion factors where appropriate. All uses of the chemical are summed to generate total exposure. A single estimate of mean dietary exposure for the whole population is the outcome.

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 agricultural and veterinary chemicals may also be conducted using the DIAMOND program but would generally only happen if exposure estimated using the NEDI were approaching the ADI. As noted earlier, use of DIAMOND allows a more refined estimate of dietary exposure.

When exposure estimates are produced for international agencies or meetings, the values estimated are referred to as the IEDI or International estimated dietary intake. The consumption data used for the IEDI are WHO cluster diets (FAO/WHO, 2008).

Chronic dietary exposures (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 agricultural chemicals currently being used, to establish ERLs.

5.4.2 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 agricultural and veterinary chemicals where an ARfD has been established. The general principles applying to acute dietary exposure assessments have been previously outlined (Section.4.4.1). FSANZ uses deterministic modelling techniques to estimate acute dietary exposure to agricultural and veterinary chemicals.

To date, all acute dietary exposure assessments have been 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. Additionally, it is also unlikely that the same chemical is present on two or more commodities consumed at the same time.

Food chemical concentration data used

The national estimated short term intake (NESTI) is used to estimate acute dietary exposure according to the methodology described by the 2000 Meeting of the JMPR (WHO, 2008). By international convention, the highest residue found in residue trials is used to estimate a 'worst case' exposure. Where relevant, this figure may be adjusted for processing effects. 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.

Food consumption data used

In contrast to the use of mean consumption amounts in estimation of chronic dietary exposure to agricultural and veterinary 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.

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, and those aged 2-6 years. Consumption amounts for groups of raw commodities (e.g. citrus fruits as opposed to oranges) are also provided. These consumption data are derived from the 1995 NNS.

In some instances, particularly when considering population subgroups, there may be insufficient consumer numbers (39 or fewer) to allow the derivation of a robust 97.5th

percentile consumption amount for the large portion. In these cases the large portion size can be replaced by the large portion size for a closely related commodity 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). Appendix 5 outlines a decision process for selecting the large portion amount.

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 5.

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.

The NESTI is calculated separately for the whole population and for small children aged 2-6 years.

JECFA model diet for exposure assessments of veterinary drug residues

For international purposes, assessment of dietary exposure to residues of veterinary drugs uses a model diet that represents the upper limit of the range of daily consumption for individual edible tissues and animal products:

300 g meat (as muscle tissue)
100 g liver
50 g kidney
50 g tissue fat
100 g egg
20 g honey
1.5 litre milk (FAO/WHO, 2008).

These consumption amounts are 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 is summed for all relevant tissues to produce an Estimated Daily Intake (EDI).

5.5 Novel foods and ingredients

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

- Novel foods and ingredients 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 the application relates.
- The assessment may consider market share information and predicted consumer behaviour.

Dietary exposure assessments for novel foods are conducted in a very similar way to those for food additives. However there is often no reference health standard for novel foods. In this case, risk characterisation will proceed as for an additive for which there is no ADI (see section 3.6.1). Evidence provided to support a function for the novel food may include information on the intake required to achieve a certain health function, in which case this may be used in place of the reference health standard to assess whether a suitable intake can be achieved through the proposed food use.

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 are assigned to the food consumption data to determine dietary exposure prior to introduction of the novel food. 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 must be 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 DIAMOND, using the proposed use levels provided by the applicant, in addition to the baseline exposure (where relevant).

Food consumption data

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

Reporting

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.

5.6 Nutrients

The dietary exposure assessment procedures for nutrients differ from those for other food chemicals, because for nutrients we 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 after fortification.
- Intakes from supplements and other sources need to be considered in the assessments, to the extent possible.

5.6.1 Data sources

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 the NNSs were accompanied by detailed databases that provided nutrient concentration data for every food consumed in the survey. These survey nutrient databases are included in DIAMOND and used to estimate 'baseline' nutrient intakes. These data are generally derived from analytical survey data, not from maximum permissions under the Code, although other data sources such as label information and recipe calculation may also be used.

The Australian NNS databases are called AUSNUT and were released separately to the survey results, in 1999 (for the 1995 survey) and 2008 (for the 2007 children's survey). The 1995 survey reported on intake of 28 nutrients and 37 nutrients were reported in 2007. The New Zealand survey databases have not been published independently of the NNS results. These surveys reported up to 47 nutrients in the 1997 survey and 40 nutrients in the 2002 children's survey.

At times FSANZ needs to generate data for nutrient components that are not included in the survey databases. These data may be taken from national food composition databases, commissioned analytical surveys (subject to time and funds), overseas food composition tables, or may be calculated or imputed using established techniques (e.g. see Greenfield & Southgate, 2003). The origin of these data will be identified in dietary exposure assessment reports.

The treatment of 'non-detected' values for nutrients measured in analytical surveys varies depending on the nutrient and the magnitude of the LOQ in relation to typical concentrations of that nutrient. For example for many 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 in any case (for example, vitamin E in water-based beverages). However for some nutrients, typically trace minerals, a non-detected result may be assigned a value of half the LOQ as minerals are typically widely distributed in foods and the very low levels found in many foods compared to the LOQ for these minerals, may make in important contribution to intake that should be accounted for.

Limitations of nutrient data

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 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
- changes in import patterns for foods.

Reported nutrient values can also vary between data sources due to changes in analytical techniques or modes of expressing nutrients. 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.

Scenario nutrient levels for fortification assessments

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 without leading to excessive intakes in one or more population sub-groups.

Food consumption data

Nutrient concentration data are prepared (either in survey databases or specifically for the assessment) for each food consumed by each individual in the NNSs. Therefore the consumption data for each food as reported in the NNS is used for the dietary intake assessment. Consumption is totalled over a day for each individual, not by eating occasion.

5.6.2 Dietary modelling approach

Dietary modelling techniques such as the per capita data approach are generally not used in Australia or New Zealand for reasons outlined previously (see section 4.2.1). 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 national nutrition surveys means that a better data source is readily available even without the use of dietary modelling software such as DIAMOND.

FSANZ routinely uses the individual survey record approach to dietary exposure assessments where a nutrient is widespread in the food supply. DIAMOND is used for this purpose but the specific modelling techniques are somewhat different to those previously described, and are detailed below.

Model diets may be used for children under the age of 2 years (Australia) or 5 years (New Zealand). 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.

A nutrient intake assessment is a chronic exposure assessment because we are interested in long term, but not lifetime, intakes of a nutrient. 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 DIAMOND is the ability to make statistical adjustments to predicted nutrient intakes because of the existence of two 24-hour recalls for a subset of survey respondents, and for all respondents in the 2007 Australian NNS. This feature is described in section 4.5.1.

Reporting of results

Table 3 sets out the reporting conventions for nutrient dietary intake assessments. Consumer exposure is not generally reported separately to respondent exposure as almost every respondent will be a consumer of the nutrient in question because of the widespread distribution of nutrients in foods. However consumer exposure may be relevant in the modelling 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 gender categories set out in NRVs (NHMRC, 2006). 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 a separate set of reference values is often established to reflect the increased nutrient needs of pregnancy and lactation. Because NRVs are not expressed on a body weight basis, the dietary exposure estimates are not expressed on a body weight basis.

The percentage contribution to exposure 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.

Comparison of nutrient intakes with NRVs

In general, FSANZ uses the Estimated Average Requirement (EAR) Cut Point Method (NRC, 1986) to estimate the prevalence of inadequate intake. 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. For most minerals, this is the case (Health Canada, 2006; FNB:IOM, 2000a).

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. 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 subgroups 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.

FSANZ uses the Upper Level (UL) of intake to assess excess nutrient intakes. The proportion above the UL for each population group is usually estimated. 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 end point and data used to set the UL.

Other NRVs such as Suggested Dietary Targets (SDTs) and Acceptable Macronutrient Distribution Ranges (AMDRs), which relate to chronic disease risks, are also used where appropriate and relevant to the assessment.

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 1995), New Zealand food and nutrition guidelines (e.g. Ministry of Health, 2003a) and World Health Organisation guidelines.

The contribution of nutrient supplements to nutrient intakes

Predicted nutrient intakes may not be accurate where the use of nutrient supplements is common and is not taken into account.

The 2002 and 2007 children’s NNSs included quantification of dietary supplements by brand name, enabling inclusion of supplements in intake assessments. The 1995 Australian NNS included questions on supplement use but did not quantify intake or sufficiently identify supplements to enable quantitative assessments to be undertaken. In Australia in 1995/96, the then ANZFA, working with the Australian Bureau of Statistics, completed a survey of nutrient supplement use in Australia, although there are a number of data problems with this survey that limit its usefulness. This survey cannot be used to derive total nutrient intakes from food and supplements on an individual record basis as it was not the same sample that was used for the 1995 NNS.

An assessment of the contribution of nutrients from known dietary supplements and generic dietary supplements (those not known accurately to participants) was produced for the 1997 New Zealand NNS. The survey also collected significant qualitative information on supplement usage.

5.7 Processing aids

FSANZ generally does not conduct dietary exposure assessments for processing aids as processing aids do not normally remain in the food after production. However if necessary, FSANZ will use the same principles and procedures that are used for food additive dietary exposure assessments, outlined earlier.

6. LIMITATIONS, ASSUMPTIONS AND UNCERTAINTIES

This section includes information on assumptions and limitations of dietary exposure assessments. The items discussed below are general and can relate to dietary exposure assessments for any food chemical. Of fundamental importance is the understanding that, whatever the consumption data, concentration data or methodology used, dietary exposure estimates are just that, estimates, and can never capture exactly what is eaten, or what is present in foods, at any given time. In essence, survey data are snapshots that are used to predict exposure under other circumstances. Therefore dietary exposure estimates will always have associated uncertainty.

To avoid misinterpretation of dietary exposure assessment results, FSANZ documents assumptions and limitations in its assessment reports.

6.1 Limitations of food consumption data used by FSANZ

As noted earlier, NNS data are the best data sets available to FSANZ for quantifying dietary exposure to a wide range of food chemicals (see section 3.2.1). However there are a number of important limitations with NNS and other survey data that must be borne in mind when interpreting dietary exposure assessments.

Limitations depend on whether the dietary method was retrospective (food frequency, recall) or prospective (3-7 day diary records or weighed records). Both may include memory errors, reporting and coding errors and, for prospective methods, errors due to potential changes in dietary behaviour as a result of participation in the survey (Armstrong et al, 1992).

National dietary surveys tend to be designed to estimate dietary exposures for nutrients, therefore they may have additional limitations when used to estimate dietary exposure to food chemicals other than nutrients.

6.1.1 Age of the data and changing consumption patterns

The 1995 and 2007 Australian NNSs, and the 1997 and 2002 New Zealand NNSs, are the most recent comprehensive sets of quantitative data on food consumption patterns currently available to FSANZ. Conducting dietary modelling using these food consumption data provides the best estimate currently available of dietary exposure across our 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 studies become available. FSANZ is still investigating whether it is appropriate to replace the 1995 NNS consumption data for Australian children aged 2-16 years with those from the 2007 NNS in all dietary exposure assessments. It is likely that exposure or intake from both the 1995 and 2007 NNSs will be reported for this age group during the initial stages of using the data.

While the older NNSs may not include information regarding food products that are now available in the market, for staple foods such as breads, cereals and milk, the data derived from the 1995 and 1997 NNSs are likely to be still representative today. Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, appears to have been fairly stable between the 1983/1985 and 1995 Australian NNSs, although there were a few notable changes including small increases in cereals and fish consumption among adults (Cook *et al*., 2001a). In many assessments, FSANZ models exposure using broad commodity groups (e.g. milks) so that changes within a category (e.g. from full fat to low fat milk) are of no significance if total consumption within that category is largely unchanged.

There is greater uncertainty when assessing consumption of foods that have been introduced to the market since the NNSs were conducted, or for which there may have been changes in food consumption.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the 1995 Australian and 1997 and 2002 New Zealand NNSs, there have been significant changes to the Code to allow more innovation in the food industry. 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 these surveys. Since the data were collected for the 1995-2002 NNSs, there has been an increase in the range of nutrient-fortified products. 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 qualitative 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. Some of these data sources are set out in section 3.2.1.

For some product segments, NNS data from the 1990s 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.

6.1.2 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.

6.1.3 Short term consumption data representing long term consumption

Section 4.5 discussed the difficulties of using one 24-hour food consumption record to represent a population's habitual food consumption patterns. These sections also discuss the approaches FSANZ has developed to account for these difficulties.

6.1.4 Low consumer numbers

There are some foods reported in the NNSs for which the number of people who ate the food 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.

There may also be insufficient consumers of a particular food within a certain age group to enable robust estimates to be produced for exposure in that age group. This is most likely to be an issue for children aged 2-3 years in the 1995 NNS.

6.1.5 Assessments for special population groups

The NNS was not designed to capture information on food consumption during pregnancy and FSANZ is not able to model exposure in pregnant women. As an alternative, FSANZ will generally model exposure among women aged 16 – 44 years, as a proxy for pregnancy. Clearly, however, this does not take into account any significant changes women might make to their diets during pregnancy, such as stopping or reducing consumption of alcohol, caffeinated beverages and soft cheeses. The effects of such changes are considered on a case by case basis where relevant.

Other surveys, such as the Longitudinal Study of Australian Women, may include some information on dietary patterns during pregnancy and lactation that may be able to be used to interpret the dietary exposure assessment findings derived from NNSs.

FSANZ has not, to date, modelled dietary exposure according to country of birth or ethnicity, other than for Maori and Pacific people in New Zealand. This is because ethnicity does not necessarily determine eating patterns, and also because there may be insufficient respondent numbers from some ethnic groups in NNS data to enable robust assessments to be made. Studies of migrant groups indicate that there are varying degrees of change in diet when a migrant arrives in a new country (Webb & Manderson, 1991). Newer migrants and elderly people tend to retain their own traditions, though this is very dependent on where they settle, the people with whom they associate and availability of traditional foods and cooking equipment.

DIAMOND does have the capability to model for different eating patterns which could be used if appropriate. For example, a model could be run for ‘high rice eaters’ as a proxy for an ‘Asian style’ diet.

In Australia there are limited data available on the dietary patterns of Aboriginal and Torres Strait Islander peoples. In national surveys, the sample size for any population group which forms only 2-3% of the total population, such as Indigenous Australians and people with specific health issues, is usually too small to provide a statistically viable sample. The NZ 1997 NNS and 2002 CNS over sampled Maori and Pacific people on order to obtain robust information on their dietary intakes and nutritional status.

No NNS data are available for New Zealand children aged 2-4 years. Dietary exposure assessments produced for Australian children aged 2-4 years will be assumed to be applicable to New Zealand children, unless there is clear evidence to the contrary.

6.2 Limitations of food chemical concentration data

FSANZ will never have available a ‘perfect’ data set that has accurate and current values for all food chemicals of interest, for all foods reported as consumed in NNSs. There will always be limitations with the food chemical concentration data set. Many of the issues associated with compilation of food chemical concentration data sets are identified in section 3.1.

6.3 Assumptions

Assumptions are necessary in all FSANZ’s dietary exposure assessments, as discussed in several earlier sections of this paper. This is generally due to incomplete or old data sets. 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, protective assumptions are generally used to ensure that the dietary exposure assessment does not underestimate exposure. Assumptions for nutrient intake assessments may be slightly different given that exposure should not be over- or under-estimated.

Assumptions can be general in nature, or can relate specifically to concentration data, consumption data or consumer behaviour. All assumptions made for a dietary exposure assessment are noted in the assessment report.

6.4 Uncertainty

Assessment of uncertainty in dietary exposure assessments is a developing area internationally (for example, see IPCS, 2008) and one where FSANZ is still developing its approach.

In a FSANZ dietary exposure assessment, a single food chemical concentration is generally reported for a particular food. In reality, this single value has an unstated uncertainty associated with it. In future 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.

At present, FSANZ does not quantify the uncertainty associated with its dietary exposure assessments as there are insufficient data available to enable this to happen. However sources of uncertainty are identified and a qualitative assessment may be produced at times. 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.

6.5 Validation of exposure assessments

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

- Checking chemical concentration levels and translations 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.

7. REFERENCES

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ABBREVIATIONS

ABS	Australian Bureau of Statistics
ADI	Acceptable daily intake (food additives and agricultural & veterinary chemicals)
AI	Adequate intake (for nutrients)
AMDR	Acceptable macronutrient distribution range (for nutrients)
ANZFA	Australia New Zealand Food Authority
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute reference dose
ATDS	Australian Total Diet Study (formerly the AMBS and the Australian Total Diet Survey)
AUSNUT	Nutrient composition database used with national nutrition surveys
CAC	Codex Alimentarius Commission
CCFAC	Codex Committee on Food Additives and Contaminants
CCPR	Codex Committee on Pesticide Residues
DIAMOND	Dietary Modelling of Nutritional Data (FSANZ software program)
EAR	Estimated Average Requirement (for nutrients)
FAO	Food and Agriculture Organisation of the United Nations
FSANZ	Food Standards Australia New Zealand
GAP	Good agricultural practice (relates to the use of agricultural chemicals)
GEL	Generally expected level (for contaminants)
GLP	Good laboratory practice
GMP	Good manufacturing practice (relates to use of food additives)
GRAS	Generally regarded as safe
GSFA	(The Codex) General Standard for Food Additives
HR	High residue (for agricultural & veterinary chemicals)

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 in foods)
MOH	New Zealand Ministry of Health
MPL	Maximum permitted level (for food additives)
MRL	Maximum residue limit (for agricultural & veterinary chemicals)
NHMRC	National Health and Medical Research Council
NMU	Nominated manufacturers usage (used in DIAMOND, mainly for food additives)
NNS	National Nutrition Survey
NOEL	No Observable Effect Level
NRS	National Residue Survey
NRV	Nutrient Reference Value
NUTTAB	Australian reference nutrient composition database
PMTDI	Provisional maximum 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)
STMR	Supervised trial median residues (for pesticides)
TDI	Tolerable Daily Intake
UL	Upper Level (for nutrients)
WHO	World Health Organisation

APPENDICES

Appendix 1. DIAMOND – the FSANZ computer program for conducting dietary exposure assessments

The DIAMOND program is a custom made, stand alone program mostly used for FSANZ's core work of developing and amending food standards. It is also used for many other purposes, for example to conduct the dietary exposure assessments for the Australian Total Diet Survey. DIAMOND stands for **DI**et**A**ry **M**odelling **O**f **N**utritional **D**ata.

Development of the program began in 1996, before which dietary exposure assessments were done by hand or using spreadsheets and food consumption data on a population basis. The program runs on a dedicated server at FSANZ. DIAMOND is programmed using SAS statistical software, version 9.1, by a contracted SAS programmer who makes modifications and developments to the program when required. The DIAMOND user interface is very easy to use, with drop down menus, tick boxes and text boxes, so that the everyday users of the program do not need to know the SAS programming language.

DIAMOND is able to conduct exposure assessments for food additives, agricultural or veterinary chemical residues, contaminants, nutrients, novel foods and other food ingredients.

The program is able to run models for different age/gender groups, and different ethnicities. It is also possible to select respondents with particular dietary patterns and run models specifically for them (e.g. high rice eaters, non-meat eaters etc).

There are two main sections of the DIAMOND program:

- the data section, where all of the data required for conducting dietary exposure assessments are stored
- the chemical modelling section, where the chemical being assessed is selected and the parameters for the model are set up (e.g. age/gender groups), run and reported.

The data section of DIAMOND includes:

- lists of all food chemicals that can be modelled, and their relevant reference health standards (RHS)
- the maximum permitted concentration of food chemicals as per the Code
- other food chemical concentration data such as manufacturers use levels for additives, trial data and processing factors for agricultural and veterinary chemicals, survey data and monitoring data for contaminants, and nutrient composition datasets
- the data from National Nutrition Surveys (NNS) from Australia (1995 & 2007) and New Zealand (1997 & 2002), including the list of food codes and names for all foods consumed, food consumption data, body weight, age, gender and ethnicity for each survey respondent
- food classification systems, including the classification of raw commodity foods for pesticide and contaminant assessments and the Australia New Zealand food classification system for food additives

- 'translation' data sets where the foods people consumed in the dietary surveys are mapped to the most appropriate food classification. The foods from each NNS are mapped to both the raw commodity and food additive classification codes
- a recipe database for those mixed foods that don't fit exactly into the classification codes, for which a recipe is used to break down these foods into ingredients that do fit into the classification codes. For each NNS there is one recipe dataset for the food additive models, and one for the pesticide and contaminant models.

There is also a set of hydration factors and raw equivalence factors associated with the NNS foods. Hydration factors are used to ensure that for food additive models, all foods translated in one classification code are all in the same form, i.e. all cordials are made up, coffee and powdered beverages are prepared. For food additives, the concentration permitted refers to the food as prepared for consumption, according to the Code, and therefore food consumption amounts reported in the NNS need to be converted into this form. For pesticide and contaminant models the raw equivalence factors again ensure all foods are in the same state, the raw state, i.e. all meat is converted to raw weights, all yoghurt, cheese etc are converted to milk equivalents and fruit juices to raw fruit.

The DIAMOND program has a number of different models that can be run:

- budget method models for food additives
- high consumer model
- chemical intake model that uses the individual dietary records from each respondent in the NNS
- two nutrient intake models that estimate nutrient intakes and also allows scenario nutrient concentrations to be modelled. There is one model that estimates intakes based on a single day of food consumption data (or the average of two days if using the 2007 NNS), and a second that estimates adjusted intakes based on a second day of food consumption data for a subset of survey respondents
- food intake model that simply allows extraction of food consumption data from NNS foods, in whatever combination is required.

While DIAMOND has specific models that can be run, sometimes the assessment needs to be done a little differently, or results are required that DIAMOND does not produce under its standard programming. In these situations, a specific ad hoc program is written by the SAS programmer to enable the required assessment to be conducted.

Reporting of DIAMOND results

There are many results produced by the DIAMOND program. Results may be reported for all respondents (i.e. all people from the dietary survey for the age/gender group being assessed) and/or for consumers only (i.e. only those survey respondents that consumed the food chemical being assessed). The results produced by DIAMOND include:

All Respondents	Mean exposure (units/day, units/kg body weight/day, % RHS) Median exposure (units/day, units/kg body weight/day, % RHS)

Consumers only	Mean exposure (units/day, units/kg body weight/day, % RHS) Median exposure (units/day, units/kg body weight/day, % RHS) 90th or 95th percentile exposure (units/day, units/kg body weight/day, % RHS)

Other results that may be reported include:

- standard deviations
- food chemical exposure from each food group
- percentage contribution of each food group to the total estimated exposure for the food chemical
- summary food consumption information for food groups for the models
- a food list that outlines what foods were in each food group and the recipes used in the model
- a display of high or low consumers (over or under a specified level), both the number above or below and what they consumed to make them above or below that level.

Exposures for all respondents can be produced and exported to Microsoft Excel for graphing purposes. All other results can also be exported to Excel for manipulation and graphing purposes.

How DIAMOND works in general terms

Each individual's exposure to the food chemical is calculated using his or her individual food records from the NNS. The DIAMOND program multiplies the specified concentration of the food chemical by the amount of food that an individual consumed from that group in order to estimate the exposure to the food chemical from each food. Once this has been completed for all of the foods specified to contain the food chemical, the total amount of the food chemical consumed from all foods is summed for each individual. Population statistics (mean, median and high percentile exposures) are then derived from the individuals' ranked exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individual's total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived. A small number of NNS respondents did not provide a body weight. These respondents are not included in calculations of estimated dietary intakes that are expressed per kilogram of body weight.

Where estimated exposures are expressed as a percentage of the reference health standard, each individual's total exposure is calculated as a percentage of the reference health standard (either using the total exposures in units per day or units per kilogram of body weight per day, depending on the units of the reference health standard), the results are then ranked, and population statistics derived.

Application of sampling weights

Sampling weights are numerical factors used to take account of a survey respondent's probability of selection in the survey, considering factors relevant to that survey. Typically this may include age, gender and location of residence, and sometimes ethnic origin, income and education level. When NNSs are released, a weight is provided for each individual in the survey that indicates the number of people in the nation that are represented by that one survey respondent. For example, if a respondent were assigned a weight of 200, this would mean that there are 200 people in the whole population who have the same characteristics as this individual, in terms of those factors being accounted for in that particular survey (NSS, 2009).

Survey weights are only applied in DIAMOND to the data from the 2002 New Zealand and 2007 Australian children's nutrition surveys as these surveys used sampling techniques that deliberately over-sampled some sectors of the population. Data from the 1995 and 1997 Australian and New Zealand NNSs are used unweighted.

DIAMOND uses SAS's inbuilt algorithms to calculate weighted food consumption, weighted dietary exposure and the proportion of the population that consumes, or is exposed to, a particular food or food chemical respectively. DIAMOND calculates weighted results using the CHILD_WGT sampling weight from the 2002 NZ NNS and SAMPWGHT from the 2007 Australian NNS. No statistical manipulations are applied to the data to account for distributions of exposure that are not normal. Weighting is applied after all other calculations, including calculation of two-day adjustments to nutrient intake, are undertaken.

A simple example of calculation of a weighted mean is provided below.

Person ID	Exposure unweighted	Survey weight	Exposure weighted
1	8	50	=8*50
2	7	20	=7*20
3	10	10	=10*10
4	6	100	=6*100
5	9	20	=9*20
Sum	40	200	1420
Mean	**8.0**		**7.1**

In this example, the unweighted mean exposure is (8+7+10+6+9)/5 = 8, compared to the weighted exposure of 7.1.

Appendix 2. Data selection criteria used to derive representative metal concentrations for dietary exposure assessments

These data selection criteria were developed for Proposal P157 Metal contaminants in food. During the assessment of this proposal, the then ANZFA decided to select the most representative metal concentration level available, not necessarily the highest median/mean value reported from surveys, for use in dietary exposure assessments. Additional refinements to the process for collating raw data were also developed where raw data for a given commodity-contaminant combination were derived from different surveys with different reported limits of quantification (LOQs) or reporting.

These criteria are provided here as a guide to the decision making processes that are needed when collating data from different sources. However the selection of appropriate chemical concentration data for a particular dietary exposure assessment needs to be determined on a case by case basis.

The following data selection criteria were used to identify data for further consideration and to assess data quality:

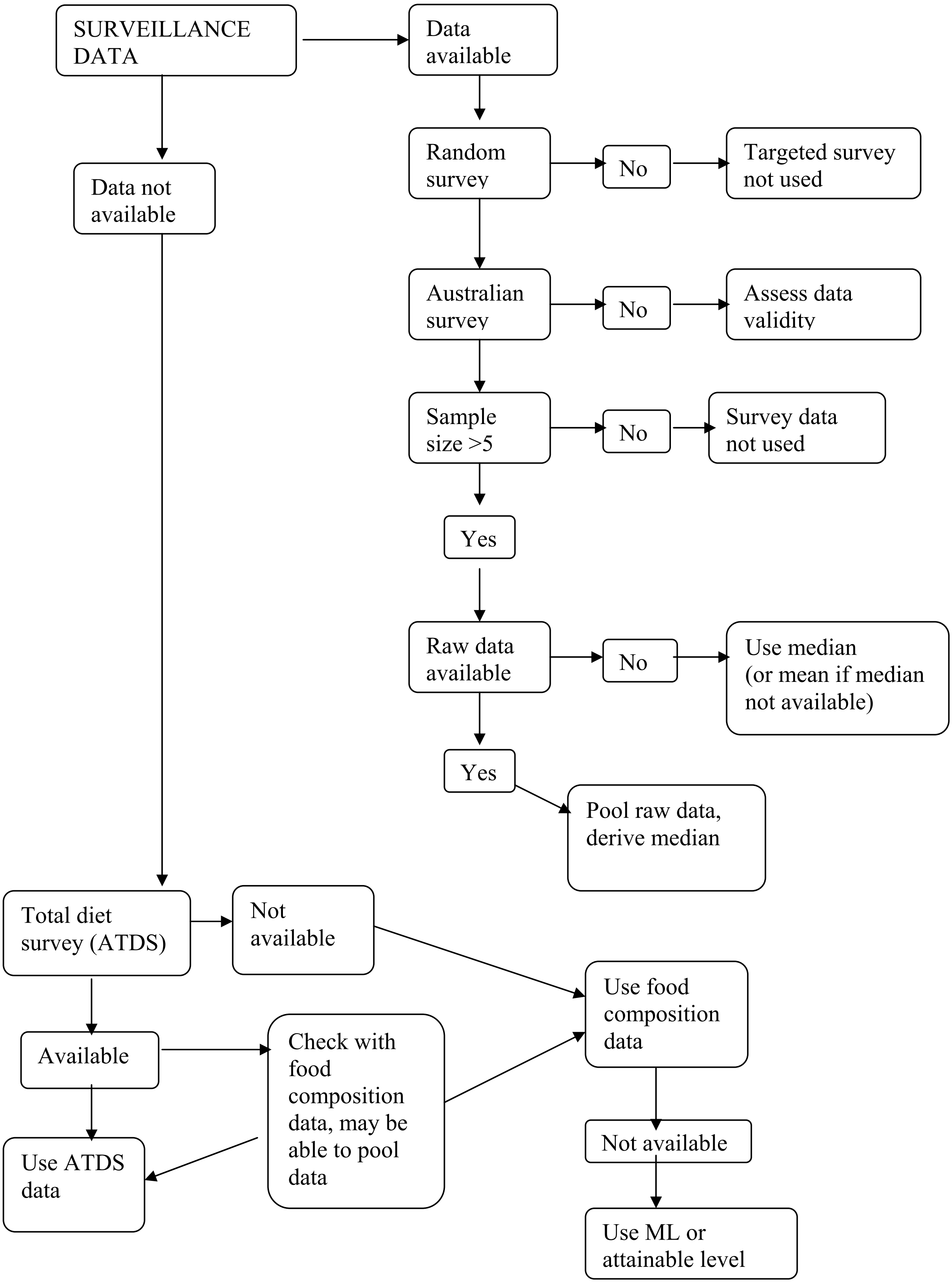
- surveys were for Australian foods
- surveys used random sampling techniques rather than targeted sampling
- foods were analysed after 1985
- sample size of >5
- raw data available as opposed to mean or median values only.

In general, the quality of reporting of survey data was not adequate, with few surveys providing all raw data points and sufficient background information (such as the survey purpose, form of foods analysed, sampling procedures, analytical techniques used and treatment of non-detect results) to enable detailed consideration.

The data available for each metal-commodity combination varied a great deal in terms of the number and type of surveys and the sample sizes and hence no strict data inclusion/exclusion rules could be developed. While in general, surveys with raw data points were preferred over surveys where only the mean or median results were reported, this was not always the case. For example, a large survey with a reported median and no raw data may have taken precedence over a very small survey with raw data. The data for each metal-commodity combination were reviewed on an individual basis and the most representative median concentration level for each metal-commodity combination selected for use in dietary models.

Figure A2.1 shows the data selection criteria.

Figure A2.1: Decision tree for selecting metal contaminant data



Appendix 3. Example of the collation of food chemical data for dietary exposure assessments – mercury in fish

Background

FSANZ undertook a dietary exposure assessment to assess the risk of excessive exposure to mercury, particularly for pregnant women and young children in New Zealand and Australia. The exposure assessment included the majority of foods in the diets of these two countries, and included a particular emphasis on seafoods, with specific fish types assessed separately.

Sources of concentration data

Mercury concentration data collected and included in the FSANZ metal contaminants database were for total mercury levels. Methylmercury is the most toxic form of mercury encountered in the diet. However surveys in Australia and New Zealand have tended to analyse for total mercury, and not the methylmercury component for reasons including method availability and cost. For this reason, the total mercury concentrations were assumed to be all methylmercury for the exposure assessment in order to assume a worst case scenario.

Mercury analytical data that were collected for an earlier assessment (Proposal P157) were used in this assessment also, with new analytical data added to the dataset. Representative mercury concentrations for each commodity were then derived from this data set.

The total number of data points for Australia, collected from 1985 onwards, was approximately 15 300, of which there were about 9 600 for seafoods. For New Zealand, the total number of data points was approximately 2 400, 2 300 of which were for seafoods.

Analytical data for mercury for a range of foods, including seafood, used in P157 were from the:

- National Residue Survey (NRS) (Australia)
- Australian and New Zealand Total Diet Studies
- Australian Government Analytical Laboratories (AGAL) (now the National Measurement Institute (NMI)).

New data on mercury in seafood were collected by FSANZ in 2003. These data were obtained from three Australian states (NSW, Victoria, Western Australia), the Australian National Residue Survey, the New Zealand government and from industry.

Pooling of survey data

All of the data for individual samples that met the FSANZ data selection criteria developed during P157 (see Appendix 2) were pooled, and representative median mercury concentrations were derived for each food. Median concentrations were used for each food in this exposure assessment because the distribution of the analytical data for food contaminants tends to be positively skewed (i.e. there are a majority of lower concentrations and a few very high concentrations). This skewed distribution leads to the arithmetic mean being significantly higher than the median (or 50th percentile) value.

The foods and the median methylmercury concentration levels used in this exposure assessment are shown below in table A3.1 for a subset of foods.

Where a 'not detected' result was the median value for a commodity group, a range of concentrations between zero and the LOR was used in the exposure assessment. This is because contaminants are ubiquitous in the environment, and it cannot be assumed that the concentration in a food is zero. Concentrations for some foods and the resulting estimated exposures are therefore presented as two levels between which exposure could occur.

Medians for each type of fish were derived where there were more than 30 data points for that fish. This resulted in far more detail in the dietary exposure assessment than there was in P157, where there were only three fish groups for which mercury concentrations were derived: predatory fish, non-predatory fish and tuna. This detail was required in order to determine the best estimate of exposure and to better target specific types of fish in any resulting risk management options.

For each type of fish, three median values were derived:

- the median of the total dataset, including where there were samples exceeding the MLs from the Code
- the median of the data set that excludes samples exceeding 1 mg/kg, which is equivalent to the higher ML for fish in the Code
- the median excluding all samples over 0.5 mg/kg, the lower ML for fish in the Code, to determine whether strict enforcement of a lower regulatory limit would reduce mercury exposure.

Where there were sufficient data points for a type of fish, New Zealand concentration data were used to estimate New Zealand dietary exposure. Where there were insufficient New Zealand samples, the Australian data were combined with the New Zealand data to derive a median concentration. Where there were insufficient concentration data for Australian fish (hoki/blue grenadier, gemfish, orange roughy and sole), New Zealand data were used to 'top up' Australian data sets and medians then derived for the exposure assessment. Data obtained by FSANZ indicated that, at the time of assessment, 70% of fish imported into Australia are from New Zealand.

If there were no consumption data for a type of fish, that type of fish was separated out in the exposure assessment and contributed nothing to the exposure to mercury.

Dealing with 'not specified' fish

In the 1995 NNS, there were some fish consumed that were reported as 'fish, not further specified', where the survey respondent did not know what specific type of fish they consumed. These fish were also used in fish recipes for mixed dishes where the type of fish in the dish was not specified by the survey respondent. A concentration of mercury assigned to these 'fish not specified as to type' needed to be representative of the consumption of all fish by the population. Therefore, a weighted median concentration was calculated for not specified fish. This was done separately for Australia and New Zealand.

The weighted median was calculated by firstly deriving the consumption of each type of fish based on all NNS respondents from DIAMOND. This did not include tuna and salmon where consumers seemed to be aware that these types of fish were being consumed and therefore reported eating them. The consumption for all fish was summed, and the consumption for each type of fish was calculated as a percent of the total. The percentage was then the number of times the median for each type of fish was used in the weighted dataset. For example, if a fish had 4% of the total consumption, and this fish had a median concentration of 0.3 mg/kg, then 0.3 was entered 4 times in the weighted dataset, and a fish with a consumption of 20% had a median of 0.02 mg/kg, 0.02 was entered into the weighted dataset 20 times, and so on until medians from all types of fish had been included in the weighted data set. The 100 samples in the weighted dataset were then ranked and the median that was derived was the weighted median used for 'fish not specified as to type'. This weighted median represents the pattern of fish consumption at the time of the NNSs.

Table A3.1: Median concentrations of mercury in some foods used for the dietary exposure assessment

Food Code	Food Name	ML (mg/kg)	Australian median conc. (mg/kg)	New Zealand median conc (mg/kg)
DT0171	Tea, green, black	-	0 – 0.01	0 – 0.0028
IM	Molluscs	0.5	0 – 0.01	0 – 0.01
PM0840	Chicken meat	-	0 - 0.01	0 - 0.0028
WC0979	Prawns	0.5	0.02	0.032
WD0121	Salmon species	0.5	0.01	0.03
WD0123	Trout species	0.5	0.06	0.06
WD0890	Eel species	0.5	0.1	0.1
WD0893	Atlantic salmon	0.5	0.029	0.027
WD0898	Barramundi	1	0.1	0.028
WS0012	Fish, not specified	1	0.1842	0.135
WS0013	Dory	0.5	0.03	0.03
WS0014	Hoki	0.5	0.14	0.14
WS0015	Warehou	0.5	-	0.07
WS0131	Shark	1	0.4	0.346
WS09521	Tuna, non-canned, non-bluefin	1	0.17	0.13
WS09522	Tuna, canned	0.5	0.09	0.09

Note: This is not a comprehensive list of foods for which median values were derived; it is provided for illustration purposes only. The range of values indicate that all survey samples were 'not detected'. The lower number in the range is where not detected values were assigned a zero concentration (lower bound) and the upper number in the range is where they were assigned a concentration equal to the LOR (upper bound).

Appendix 4. Screening methods – sample calculations

Calculations using the budget method

For solid foods:

The **primary** ceiling for solid foods only is based on the assumption that a 1-2 year old child requires 50 g food/kg BW/day to meet energy requirements.

If the maximum exposure to a food additive is equivalent to the value (A), where A equals the ADI in mg/kg BW/day, then the permitted level of use of the additive in any solid food is calculated as follows:

> If A mg food additive are permitted in 50 g food/day
> then 2 x A mg food additive are permitted in 100 g food (A x 100/50), and
> 20 x A mg food additive are permitted in 1 kg food.
>
> Primary ceiling or permitted level of use of additive in any solid food
> = 20 x A mg/kg food.

For beverages:

The physiological requirement for a 1-2 year old child for fluid intake is taken to be 100 mL/kg BW/day.

If the maximum exposure to a food additive is equivalent to the ADI in mg/kg BW/day, the value (A), then the permitted level of use of the additive in any beverage is calculated as follows:

> If A mg food additive are permitted in 100 mL beverage/day
> then, 10 x A mg food additive are permitted in 1 litre beverage
> (A x 1000/100).
>
> Primary ceiling or permitted level of use of additive in any beverage
> = 10 x A mg/litre beverage.

For additives present in both foods and beverages, then the ADI is shared proportionately between the two, according to food consumption data where:

$$A = A_f + A_b$$

(where, A_f = A x proportion of solid foods in diet, A_b = A x proportion of beverages in diet)

Outcome: if an additive is used to achieve technological function at levels below the calculated primary ceiling in all food and beverages, then it is assessed as ‘acceptable’ (not of a public health and safety concern). In cases where the required technological use of the food additive is greater than the calculated primary ceiling, then the modified budget method should be used.

Reverse budget method

Amount food (kg) = ADI (mg/kg) x body weight (kg)/MPL (mg/kg food)

High consumer method

The high consumer method can be used to estimate the highest potential exposure to a food chemical from the total diet, by identifying the two representative foods which are likely to contribute the highest levels of the food chemical exposure to the total dietary exposure, where:

Total food chemical exposure = ∑ (two highest consumer food chemical exposures from representative foods + mean population food chemical exposures from other foods)

and

Mean exposure of food chemical from specified food = mean consumption of food x median food chemical level for commodity

(refined according to information on market share, processing, food preparation)

Theoretical Maximum Allowable Levels (TMAL)

TMAL =

$$\frac{\text{Reference health standard (units/kg bw) – Exposure from all other foods (units/kg bw) * Mean Bodyweight (kg)}}{95^{th}\text{ Percentile food consumption (kg)}}$$

Examples of Budget Method and Dietary Exposure Assessment Calculations

Table A4.1: Additive permissions for saccharin used in the dietary exposure assessment

ANZFCS Code	Food Code Description	Maximum Code level (MPL) (mg/kg)
4.3.3	Canned or bottled fruits & vegetables	110
4.3.4	Fruit & veg spreads, incl. jams	1 500

5.2	Chewing gum, low joule	1 500
11.4.1	Table top sweeteners, liquid	GMP
11.4.2	Non-sugar sweeteners, tablets, powder, granules	GMP
14.1.2.2	Fruit & veg juices & products, low joule	80
14.1.3	Water based flavoured drinks	80
14.1.3.1	Brewed soft drinks	50
20.2	Sauces/topping/dressings/mayonnaise	1 500
20.2	Soup bases	1 500

* Topping

Budget method approach

The results of the BM and MBM for saccharin are given in table A4.2. The assumptions made in the calculations are:

- saccharin is used 50% in food and 50% in beverages (BM)
- only 50% food and 50% beverages contain food additives (MBM).

Table A4.2: Maximum predicted levels for saccharin

	Food (mg/kg)	**Beverages, as consumed (mg/kg)**
Maximum Code level (MPL)*	range 110 – 1 500	range 50 - 80
Budget method Theoretical Maximum Level (TML)	50 (20 x 0.5)	25 (10 x 0.5)
Modified budget method Maximum Technological Use Level (TUL):TML	TML: 100 (i.e. 50x2) TUL: 15 (1500÷10)	TML: 50 (i.e. 25x2) TUL: 1.6 (80÷50)

NOTE: A is the numerical value of the ADI in mg/kg BW/day (ADI for saccharin is 5 mg/kg body weight)
* From Table A4.1

Outcome: required levels of use for technological function are higher than the maximum level estimated by the budget method. screening more detailed and refined dietary exposure assessment is required.

High consumer model

In the high consumer model, it is assumed that saccharin is present at MPLs in all products where it is permitted to be used, according to Standard 1.3.1. It is also assumed that all food products in the category contains saccharin, that is, no account is taken of the market share between different sweeteners.

In the refined high consumer model, manufacturers' use levels replace MPLs, while other assumptions remain the same. Market share data was not used to weight the mean level of saccharin in products.

The DIAMOND program was used to estimate saccharin dietary exposures. Results for the high consumer model for Australians aged 2 years and above are given in table A4.3. Permissions for additive used in the model are given in table A4.1. Food consumption data were taken from the 1995 National Nutrition Survey.

Table A4.3: Estimated dietary exposure to saccharin using the high consumer model

Estimated additive dietary exposure	Additive used at maximum permitted levels (MPL)	Additive used at nominated manufacturers' level (NMU)
mg/day	1 611	1 072
mg/kg BW/day	24	16
% ADI	480	320

Outcome: predicted dietary exposures for saccharin from the whole diet exceed the ADI. It is also possible for a high consumer of one product only (e.g. table top sweeteners) to exceed the ADI. The next step of undertaking dietary exposure estimates derived from population surveys is required.

Individual record survey approach

Dietary exposure estimates for saccharin are given in table A4.4. Results are based on individual dietary records from the 1995 NNS.

Table A4.4: Estimated dietary exposures to saccharin, calculated using individual dietary records

	Additive used at maximum permitted levels (MPL)	Additive used at nominated manufacturers' level (NMU)
All respondents 2+ years		
Mean mg/day	15	12
(%ADI)	(4)	(3)
Consumers only 2+ years		
Mean mg/day	93	73
(%ADI)	(259)	(20)
95^{th} percentile mg/day	375	263
(%ADI)	(95)	(70)

***Outcome**:* estimated mean dietary exposures for all respondents and consumers did not exceed the ADI assuming MPLs in all food categories permitted to contain saccharin (4% ADI and 25% ADI respectively). Replacing MPLs with nominated manufacturers' use levels resulted in estimated mean dietary exposures for all respondents and consumers only also below the ADI (3% ADI, 20% ADI respectively). For high consumers, predicted dietary exposures were close to the ADI for MPLs (95% ADI) and lower using nominated manufacturers' use levels (70% ADI).

Appendix 5. Calculation of acute dietary exposure for agricultural and veterinary chemical residues

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 (JMPR 2003).

There are four equations used to calculate the NESTI (WHO, 2008). 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.

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

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 supervised trial median residue level indicated by composite sample data.

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

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.

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

Case 3

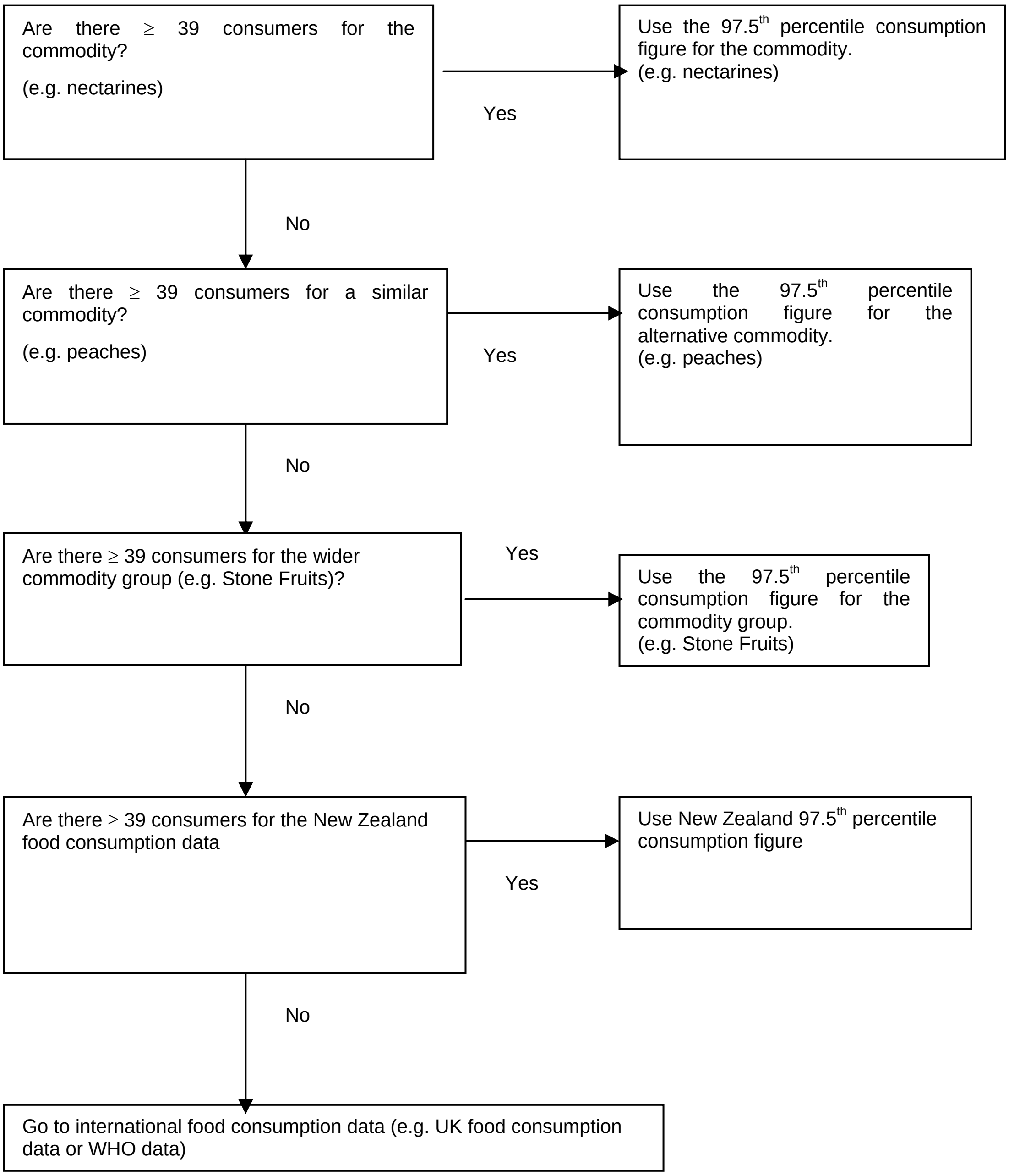
For commodities that are basically "homogeneous" when consumed due to the fact that they are centrally processed (e.g. cereals, milk), the use of a variability factor is not considered necessary. Due to the bulking and blending involved in the central processing, the best indicator of the residue level 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.

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

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.

Flow chart for the 97.5th percentile consumption data selection for acute dietary exposure assessments



Appendix 6. 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 substance in food or drinking water, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable risk to health. The ADI is listed in units of mg/kg bw/day (FAO/WHO, 2006).
Aggregate exposure	An estimate of exposure to a single food chemical taking into account all known sources of the chemical (e.g. food, air, water etc).
AI	Adequate intake. The average daily nutrient intake levels 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, 2006).
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.
Consumer	A respondent in the NNS who ingests (i.e. is exposed to) the food chemical being assessed via food eaten.
Consumer behaviour model	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	Used in this document to indicate food and beverage consumption.
Cumulative exposure	An aggregate exposure assessment for two or more chemicals that have the same mechanism of toxicity.
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 amount of a food chemical other than a nutrient that is ingested by a consumer from food.

Dietary intake The amount of a nutrient that is ingested by a consumer. This can be via food and/or dietary supplements.

EAR Estimated average requirement. A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group (NHMRC, 2006). Used to assess the adequacy of dietary intakes of populations.

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 quantitative and/or qualitative evaluation of the degree of the likely intake of an agent via food as well as exposures from other sources if relevant. 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, agricultural and veterinary chemicals, nutrients, novel ingredients and other food chemicals (e.g. caffeine).

Good agricultural practice The officially recommended or authorised use of such substances (pesticides), under practical conditions, at any stage of production, storage, transport, distribution, or processing of food, agricultural commodities, or animal feed, bearing in mind the variations in requirements within and between regions (UNEP/FAO/WHO, 1989).

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 a combination of both.

LOD Limit of detection. The lowest concentration of a chemical that can be qualitatively detected using a specified laboratory method and/or item of laboratory equipment (i.e. its presence can be detected but not quantified).

LOQ Limit of quantitation. 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.

LOR Limit of reporting. The lowest concentration level that the laboratory reports analytical results.

Market weighted	A concentration or exposure estimate that has the proportion of the market or food group containing the food chemical of interest taken into consideration.
Mean	Arithmetic mean (unless otherwise specified).
ML	The maximum level, expressed as milligram per kilogram, is the limit placed on the level of a contaminant, such as a heavy metal, in food in the 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 PTDI or PTWI.
MRL	Maximum residue limit. 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.
PMTDI	Provisional maximum tolerable daily intake. The endpoint used for contaminants 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, 2006).
Probabilistic dietary exposure assessment	A dietary modelling 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.

PTMI	Provisional tolerable monthly intake. 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, 2006).
PTWI	Provisional tolerable weekly intake. An 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, 2006).
RDI	Recommended dietary intake. The average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group (NHMRC, 2006). Used to assess intakes of individuals.
Respondent	Any person included in the NNS. The number of respondents will vary according to the survey (for example there were 13858 respondents to the Australian 1995 NNS aged 2 years and above, and 4636 respondents to the New Zealand 1997 NNS aged 15 years and above). This term may also be used to refer to the number of respondents within a particular sub-population group.
Reference health standard	A level to which dietary intake or exposure estimates are compared. Can indicate a level of essentiality or toxicity.
Risk analysis	A process consisting of three components: risk assessment, risk management and risk communication.
Risk assessment	The scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation.
Sampling 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).
UL	Upper level of intake. 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, 2006).
90^{th}, 95^{th} or 97.5^{th} percentile	A level at which 10%, 5% or 2.5% respectively of the population or data points are above. The 90^{th} percentile dietary exposure to a food chemical is generally used to represent a 'high consumer' in a chronic dietary exposure assessment.