**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

**Budget Estimates 2013-14, 5/6 & 7 June 2013**

**Question:** E13-141

**OUTCOME:** 1 – Population Health

**Topic:** Memorandum of Understanding with Australian Pesticides and Veterinary Medicines Authority

**Type of Question:** Hansard Page 65, 6 June 2013

**Senator:** Xenophon

**Question:**

Please provide a copy of Food Standards Australia New Zealand's Memorandum of Understanding with the Australian Pesticides and Veterinary Medicines Authority.

**Answer:**

A copy of Food Standards Australia New Zealand's Memorandum of Understanding (MoU) with the Australian Pesticides and Veterinary Medicines Authority is attached.

The MoU was executed on 20 June 2000 under the agencies' former names, the Australia New Zealand Food Authority and National Registration Authority for Agricultural and Veterinary Chemicals respectively.

**MEMORANDUM OF UNDERSTANDING**

**BETWEEN**

**AUSTRALIA NEW ZEALAND FOOD AUTHORITY**
established pursuant to section 6 of the
*Australia New Zealand Food Authority Act 1991*

**AND**

**NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS**
established pursuant to section 6 of the
*Agricultural and Veterinary Chemicals (Administration) Act 1992*

**Objectives**

The Australia New Zealand Food Authority (ANZFA) and the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) enter into this Memorandum of Understanding with the following broad objectives:

- To ensure robust protection of public health and safety;
- To expedite decisions on Maximum Residue Limits (MRLs); and
- To ensure efficient use of regulatory resources.

**NOW IT IS AGREED AS FOLLOWS**

1. This Memorandum of Understanding relates to an arrangement between the Australia New Zealand Food Authority (ANZFA) a statutory authority established pursuant to Section 6 of the *Australia New Zealand Food Authority Act 1991* as a body corporate and the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), a body corporate established pursuant to section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

2. This Memorandum of Understanding will commence on the date of execution and will terminate on the date that the terminating party advises the other party in writing of their intention to terminate this Memorandum of Understanding.

3. This Memorandum of Understanding replaces the previous Memorandum of Understanding between ANZFA and the NRA dated 17 March 2000.

4. ANZFA and the NRA, agree that this Memorandum of Understanding can only be terminated following consultation between the person holding the position of Managing Director at ANZFA and the person holding the position of Chief Executive Officer at the NRA.

5. The officers responsible for the administration of this Memorandum of Understanding are to be, the person holding the position of Managing Director at ANZFA and at the NRA the person holding the position of Chief Executive Officer.

6. Any variation to the provisions of this Memorandum of Understanding may be proposed by either party, but must be agreed to by both parties.

7. ANZFA and NRA, agree that in undertaking the following each Party shall abide by provisions of this Memorandum of Understanding in so much as the provisions relate to them.

8. The assessment of dietary exposure to agricultural and veterinary chemicals (assessment process) shall be conducted in a manner that is both timely and consistent with the statutory obligations of each party.

9. ANZFA and the NRA agree that the assessment process will be conducted in accordance with the attached protocol (Attachment 1) and be based on Australian food consumption information.

10. ANZFA and NRA agree that in the following circumstances, the NRA will provide ANZFA with a dietary exposure assessment for the active constituent prior to making an application to ANZFA to amend the *Food Standards Code* and upon commencement, the *Australia New Zealand Food Standards Code*:

- all new active constituents; or
- all active constituents that have been subjected to a Review as part of the NRA's Review program; or
- active constituents where the calculated dietary exposure exceeds 90% of the Acceptable Daily Intake or where relevant exceeds 90% of the acute reference dose for the active constituent.

11. ANZFA and NRA agree that ANZFA will consider the dietary exposure assessment and advise the NRA within ten working days if the dietary exposure assessment has been conducted in accordance with the agreed protocol.

12. ANZFA and the NRA agree that where ANZFA does not consider that the dietary exposure assessment has been conducted in accordance with the agreed protocol then ANZFA will:

- advise the NRA that the dietary exposure assessment has not been conducted in accordance with the agreed protocol; and

- provide reasons as to why ANZFA considers that the dietary exposure assessment has not been conducted in accordance with the agreed protocol.

13. ANZFA and NRA agree that in assessing MRL applications from the NRA on an application-by-application basis, ANZFA will not duplicate the dietary exposure assessment of the NRA if ANZFA is satisfied that the dietary exposure assessment has been conducted in accordance with the agreed protocol.

IN WITNESS WHEREOF the parties have executed this Memorandum of Understanding

SIGNED on behalf of the
AUSTRALIA NEW ZEALAND FOOD AUTHORITY
by, MR IAN LINDENMAYER, Managing Director of
the Australia New Zealand Food Authority )

SIGNED on behalf of the
NATIONAL REGISTRATION AUTHORITY FOR
AGRICULTURAL AND VETERINARY CHEMICALS
By DR ALISON TURNER, Chief Executive Officer of
the National Registration Authority for Agricultural
and Veterinary Chemicals )

20/6/00

# ANZFA/NRA Protocol for dietary risk assessments for pesticide and veterinary drug residues

This protocol outlines joint Australia New Zealand Food Authority (ANZFA)/National Registration Authority for Agricultural and Veterinary Chemicals (NRA) procedures for estimating dietary exposures to pesticide and veterinary drug residues found in food as a result of the use of these chemicals on food crops and animals and the consumption of treated feed items by farm animals[1]. Insecticides, herbicides, acaricides and fungicides are included in this group of chemicals.

The protocol is based on the:

- ANZFA Draft Policy paper: Dietary modelling - principles and procedures, ANZFA 1997 developed by ANZFA in consultation with staff from the NRA, TGA and the Queensland Department of Primary Industries.
- Guidelines for predicting dietary intake of pesticide residues (revised), prepared by the WHO GEMS/Food Program in collaboration with the Codex Committee on Pesticide Residues, WHO 1997;
- Report of the Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals, February 1997, Geneva, Switzerland;
- Report of the International Conference on Pesticides Variability and Acute Dietary Exposure Assessment, 1-3 December 1998, York, Pesticides Safety Directorate, Ministry of Agriculture Fisheries and Food, UK; and
- Joint Meeting on Pesticide Residues (JMPR), General Report (Items 2.4, 3) 1999.

**The principles and procedures for dietary modelling described in this protocol for pesticide and veterinary drug residues are consistent with FAO/WHO guidelines for estimating intakes of pesticide residues. This protocol is intended for use in Australia.**

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[1] The Codex definition of a pesticide residue is: *'any specified substance in food, agricultural commodities or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities that are considered to be of toxicological significance'.*
The Codex definition of a veterinary drug residue is: *'parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned'* (CAC Procedural Manual 10th edition, Rome 1997).

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# Executive summary of agency responsibilities for dietary risk assessments

| | ANZFA | NRA | TGA |
|---|---|---|---|
| **Chronic dietary exposure: new & existing chemicals*** | Provision of raw commodity consumption data for whole population, 1995 NNS<br><br>Provision of residue data and dietary exposure estimates from ATDS, if relevant<br><br>Provision of relevant residue data from State & Territory Health Departments<br><br>Provision of food consumption data | Provision of STMR data from residue trials<br><br>Provision of residue definitions, relevant processing factors, % crop treated, where appropriate<br><br>Provision of proposed MRLs | Provision of ADI<br><br>Identification of target population groups/sub groups |
| **Acute dietary exposure: new & existing chemicals** | Provision of large portion sizes for raw commodity consumption for target population group, 1995 NNS<br><br>Development of commodity weights for single units of food in collaboration with other agencies<br><br>Provision of average body weights from 1995 NNS for target group<br><br>Provision of food consumption data | Provision of HR, STMR data from residue trials, where appropriate.<br><br>Provision of residue definitions, relevant processing factors<br><br>Provision of proposed MRLs | Provision of Acute Rfd<br><br>Identification of target population group/sub groups |

* Extraneous MRLs to be the responsibility of ANZFA

**NOTE:**
acute RfD acute reference dose
ADI acceptable daily intake
ANZFA Australia New Zealand Food Authority
ATDS Australian Total Diet Survey
ECRP Existing Chemical Review Program
MRL maximum residue limit
NRA National Registration Authority for Agricultural and Veterinary Chemicals
NNS National Nutrition Survey
HR highest residue level in composite samples of edible portion from supervised trial data
STMR supervised trial median residue
TGA Therapeutic Goods Administration

# 1. Introduction

The application of pesticides to crops, stored commodities or food animals and veterinary drugs to food animals according to good agricultural practice (GAP) may result in residues remaining on the foodstuffs at the point of consumption. Maximum residue limits (MRLs) for pesticides and veterinary drugs are determined on the basis of the use patterns necessary to control pests and/or diseases and are set to reinforce GAP.

At both national and international levels, there is now agreement that MRLs for pesticide residues in food should only be set when established scientific principles of risk assessment have been applied. Risk assessment procedures include four critical steps: (1) hazard identification, (2) hazard characterisation, (3) exposure assessment, and (4) risk characterisation.

The NRA, with the Therapeutic Goods Administration (TGA), is responsible for steps (1) and (2). ANZFA and NRA are jointly responsible for steps (3) and (4) of the risk assessment procedures necessary before MRLs for pesticide and veterinary drug residues can be included in the Australian Food Standards Code. This protocol covers steps (3) and (4) only.

# 2. Dietary exposure assessments

The risk assessment process should assess whether predicted exposure estimates of residues are lower than reference health standards (step 4). Assessment of dietary exposure and the contribution of dietary exposure to total exposure are an integral part of this process (step 3). Estimates of dietary exposure, where they are used, should therefore err on the side of caution in order not to underestimate the potential risk.

## 2.1 Dietary exposure estimates

Dietary modelling is the technique of integrating food consumption data with food chemical concentration data to estimate dietary exposure to pesticide and veterinary drug residues.

The quality of the original inputs and the range of assumptions made throughout the modelling procedure determine the accuracy of dietary exposure estimates for residues. Assumptions are generally based on internationally accepted principles. It is generally recognised that estimates tend to overestimate dietary exposure because of the conservative assumptions made.

*Residue data*

It has been agreed that NRA is responsible for providing a summary of residue data required for use in estimating dietary exposures for new chemicals, extensions of use of existing chemicals, permits, trials and minor uses as well as for review chemicals in the Existing Chemical Review Program (ECRP). Relevant reduction or concentration factors will also be provided. Appendix 2 details requirements for residue data for the purposes of dietary exposure assessments

*Food consumption data*

It has been agreed that ANZFA is responsible for providing Australian food consumption data for commodities, derived from the 1995 National Nutrition Survey (NNS) for the whole population aged 2 years and over, for use in estimating chronic and acute dietary exposures for new chemicals and for extensions of use of existing chemicals. ANZFA will also provide large portion size data for use in acute dietary exposure assessments. Appendix 2 provides further details.

## 2.2 Chronic dietary exposure estimates (new and existing chemicals)

Chronic dietary exposure is the expected population mean daily exposure to a pesticide or veterinary drug residue over a lifetime. An estimate of chronic dietary exposure is required for pesticides with an acceptable daily intake (ADI) for which an MRL is proposed. There are two possible approaches to estimating chronic dietary exposures at a national level: theoretical maximum daily intake (TMDI) or national estimated daily intake (NEDI), as detailed in Figure 1[2]. In most cases, the NEDI calculation will be undertaken, providing a better estimate of potential dietary exposure to a residue from the food supply. In general, TMDIs represent gross overestimates of actual chronic dietary exposure.

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[2] The TMDI is the maximum daily intake of pesticide or veterinary drug residue, based on the assumption of residue levels in food equivalent to the MRL, integrated with data on average daily food consumption per person (FAO/WHO 1995), where:

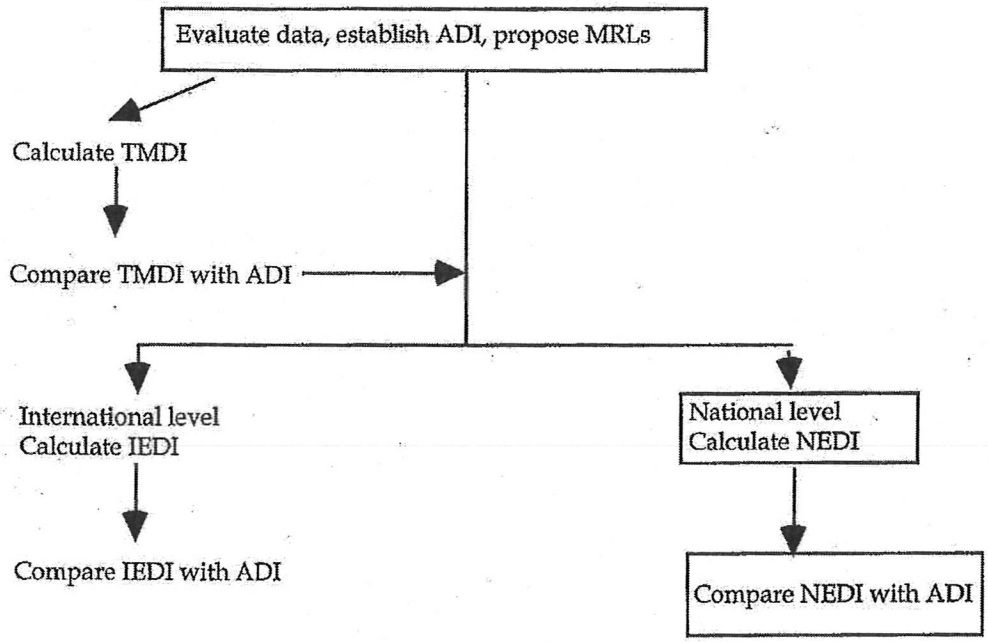
TMDI = $\sum F_i \times MRL_i$, ($F_i$ is the amount of food consumed, estimated from food balance sheet (FBS) data, and $MRL_i$ is the MRL of corresponding food commodity).

### 2.2.1 National estimated daily intake (NEDI)

A NEDI calculation makes the best use of the available data. In the case of Australia, food consumption data for raw commodities derived from the 1995 NNS (see Appendix 3) are multiplied by levels of residues found in the surveyed foods, and the estimated exposure for specific residues summed over the entire diet.

Sources of residue data are detailed in Appendix 2, and will generally be median residue data from supervised trials (STMR) for new chemicals or extension of use of existing chemicals. A variety of data sources are available to derive data for commodities where use is already permitted, such as data from State and Territory surveys, Australian Total Diet Survey (ATDS), ECRP, however, the quantity and quality of these data should be taken into account.

**Figure 1: Guidelines for estimating pesticide residue intakes (FAO/WHO 1995)**




Note:
TMDI theoretical maximum daily intake, IEDI international estimated daily intake, NEDI national estimated daily intake, ADI acceptable daily intake

Additional factors may be applied to the residue data, providing they apply to the whole commodity:

- level of residues in the edible portion of the commodity rather than the whole commodity, (STMR-P);

- reduction or concentration factors to estimate the change in pesticide residue levels due to storage, processing, preparation and cooking between the raw commodity and food as consumed (STMR-P).

For new chemicals, the NEDI can be therefore be defined as:

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

where $F_i$ is the average amount of commodity reported as consumed by whole population (national data), STMR-$P_i$ is the supervised median residue trial level of corresponding food commodity, incorporating processing/edible portion factors, where appropriate

When reliable data are available on the proportion of crop treated, a better estimate of dietary exposure to residues can be made for commodities that are sufficiently homogeneous in the food supply due to centralised processing and distribution, for example, cereal grains, processed vegetables. Similarly, the proportion of crop domestically produced and imported can be used, where appropriate.

Where the chemical is used both as a pesticide and as a veterinary chemical, all uses should be included in the model used to estimate dietary exposure.

### 2.3 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. These residues are usually considered as contaminants. Some reduction in food residues can be achieved by identifying sources of environmental contamination and adopting practices to avoid exposure as far as possible.

Chronic dietary exposure assessments will be undertaken in a similar way to existing chemicals (see above) to establish extraneous residue limits (ERLs). Extraneous chemicals should be included in the ATDS.

It is agreed that ANZFA be responsible for setting ERLs in the Australian Foods Standards Code.

### 2.4 Responsibilities of agencies undertaking joint chronic dietary exposure estimates

Information on proposed MRLs, STMR data, edible portion and processing factors is required to calculate the NEDI using the best available data. Residue data for the chemical being evaluated are required for all proposed new uses and for commodities with existing uses to enable the exposure from the total diet to be estimated. Information, such as operator exposure, environmental fate and behaviour and efficacy, submitted by agricultural chemical companies in the application to NRA is not required for the purposes of dietary modelling. Further information on the toxicology of the chemicals may occasionally be required to complete the risk characterisation.
The following commitments are required from each agency.

**ANZFA**

1. Provision of food consumption data from the 1995 National Nutrition Survey by food commodity group (according to the CCPR food classification system) for specific age/sex groups and the whole population (2 years and over).

2. Provision of residue data and dietary exposure estimates from the Australian Total Diet Survey (formerly the Australian Market Basket Survey), if available.

3. Provision of any relevant residue data submitted by the State and Territory Health Departments, if available.

4. Provision of facilities and expertise to assist in chronic dietary exposure estimates.

**NRA**

1. Provision of STMR data derived from supervised trials data submitted by the NRA applicant. Additional data may be required where the residue definition used for dietary exposure assessments differs from the definition used for establishing MRLs.

2. Provision of processing factors for chemical/commodity combinations for use in dietary modelling.

3. Provision of recommended MRLs.

4. Provision of additional toxicology data, if required.

5. In cases where a problem is perceived, provision of any relevant residue data submitted by the State and Territory Agricultural Departments, if available.

6. Provision of expertise to undertake chronic dietary exposure estimates.

**TGA**

1. Provision of an ADI and residue definitions to ANZFA and NRA (residue definition for purpose of setting an MRL may be different from that required for dietary modelling, see Appendix 1).

### 2.5 Acute dietary exposure estimates

Acute (short term) dietary exposure assessments are undertaken when an acute reference dose (acute RfD) has been determined for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis. Federal State and Territory Food regulations do not normally apply to animal products consumed directly at the farm level that are not for retail sale. Food consumption data may be required for a single eating occasion, or for a single day, depending on the nature of pesticide[2].

The national estimated short term intake (NESTI) is used to estimate acute dietary exposure (FAO/WHO 1998, Draft report 1998). First, it is necessary to determine if the commodity is homogenous or not in relation to consumption. In general, fruits and vegetables consumed in large pieces or units, where there are 3 or less commodity units per large portion, are not considered to be homogeneous commodities, for example, apples (See Appendix 2).

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[2] Time scale of 1 day (24 hours) recommended for international calculations by 1998 International Conference on Pesticide Variability and Acute Dietary Risk Assessment.

In a non-homogenous commodity where the portion size consumed in a single meal is greater than the median unit weight of that commodity it is assumed that the residue is not uniformly distributed among units. That is, it is present in the first unit of the commodity at a highest residue level in composite samples (from supervised median residue trials) and at an average level in the remainder of the portion consumed.

### 2.5.1 National estimate of short-term intake (NESTI)

MRLs are based on composite samples of a number of commodity units (number chosen according to sampling protocols) with analysis being undertaken on the mixed sample. It has been recognised for some time that there will be some variation in residue levels between the individual commodity units that comprise the composite sample. The residue level in the composite sample will not reflect the actual range of residue levels in individual units, a factor that needs to be taken into account in assessing the risk of acute dietary exposure from consuming a single portion of the commodity.

For commodities that are basically 'homogeneous' when consumed because they are centrally processed like cereals or because there are a large number of individual units per portion, for example peas, this individual variation is not considered to be of concern. However for commodities that are consumed whole or in large pieces, individual unit variability needs to be considered.

*i) Homogeneous commodity*

For a homogeneous commodity it is assumed that the residue in a single portion is distributed evenly throughout the portion. The estimated short term intake (NESTI) is calculated using the following equation:

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

where

| | |
|---|---|
| LP | full large portion size of commodity (97.5th percentile for consumers only) |
| HR-P | highest residue level incorporating processing factors/edible portion (may be MRL) |
| bw | mean body weight for target population subgroup |

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 as edible portion, for example, a banana without skin.

The application of factors for the percentage of crop or animals treated is not valid for acute assessments.

*ii) Non-homogeneous commodity*

In a non-homogenous commodity where the portion size consumed in a single meal (LP) is greater than the median unit weight of that commodity (U), it is assumed that the residue is not uniformly distributed among units. That is, it is assumed that the residue is present in the first unit of the commodity at the highest residue level (HR or HR-Pin composite samples (from supervised median residue trials) and at an average level (STMR or STMR-P) in the remainder of the portion consumed[3].

If residue trial data are available on individual crop units, then a variability factor can be derived from this data set. In the absence of individual unit data, variability factors are derived from trials using composite samples. In the composite sample with the highest value reported in the results from a supervised trial, it is assumed that the highest residue level reported from this sample is due to one commodity unit. For example, if the sampling procedures requires 10 carrots to be bulked to form one composite sample, it is assumed that one carrot in the composite sample contains the entire residue and the other 9 carrots contain no residue, a variability factor (v) of 10. This maximum residue level is termed 'HR', and may be modified by processing factors (HR-P) under certain conditions (more details outlined in Appendix 2). If residue trial data are available on individual crop units, then a variability factor can be derived directly from this data set.

In a non-homogenous commodity where the portion size (LP) consumed in a single meal is less than the median unit weight (U) of that commodity (LP<U), it is assumed that the residue is uniformly distributed.

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

where

U weight of first commodity unit

[3] Portion size is derived for raw commodities from the 97.5th percentile food consumption level for consumers only. The unit weight of a commodity is the median of typical unit commodity weights or, if not available, the mean weight of a medium-sized commodity unit (raw only).

| | |
|---|---|
| LP | full large portion size of commodity (97.5th percentile for consumers only) |
| v | "variability factor" (equal to number of commodity units in composite sample), or based on data for individual samples |
| HR-P | high residue value incorporating processing/edible portion factors |
| STMR-P | supervised median trial residue in edible portion, incorporating processing factors |

The STMR-P and HR-P residue level can only be used in acute dietary exposure estimates when the entire commodity is processed. The application of factors for the percentage of crop or animals treated is not valid for acute assessments.

### 2.6 Responsibilities of agencies undertaking joint acute dietary exposure estimates

Information on STMRs, HR data and processing factors (P) are required to calculate the NESTI. sLarge portion sizes for raw commodities and unit commodity weight data are also required. Further information on toxicology may occasionally need to be provided, particularly in cases where the acute RfD was established conservatively because specific toxicology studies required to establish an acute RfD for the chemical were not undertaken.

The following commitments are required from each agency.

ANZFA

1. Provision of food consumption data from the 1995 NNS for the 97.5th percentile consumption level (consumers only) for a specified raw commodity for the target age/sex group.

2. Assistance with the development of appropriate unit commodity weights (average weight of 1 unit of a commodity, for example 1 apple or 1 potato).

3. Provision of mean body weights for selected target population group from the 1995 NNS, for example, children aged 2-6 years, adults or whole population[4].

4. Provision of dietary modelling facilities and expertise to assist in acute dietary exposure assessment.

[4] The target population groups will be identified from toxicology studies as sub-population groups that are particularly vulnerable to the chemical or metabolites of the chemical, for example, young children, pregnant women etc.

**NRA**

1. Provision of HR, STMR, variability factor data for commodities consumed in units of four or less (for example apples), if available.

2. Provision of processing factors for chemical/commodity combinations for use in dietary modelling.

3. Provision of residue definition and identification of a target population, if applicable.

4. Assistance with the development of appropriate unit commodity weights (average weight of 1 unit of a commodity, for example 1 apple or 1 potato).

5. Provision of expertise for acute dietary exposure assessment.

**TGA**

1. Provision of an acute RfD and identification of a target population sub-group, if applicable.

## 3. Risk characterisation

In risk evaluation procedures, exposure estimates are compared with reference health standards to assess the risk of these standards being exceeded (step 4). In the assessment of the risk of chronic (long term) dietary exposure, estimates are compared to the Australian ADI. Where an acute RfD is set for a chemical, estimates of dietary exposures from a single meal or over 24 hours are compared to this health standard. In the absence of an Australian acute RfD, Codex acute RfD may be considered.

If the estimated chronic dietary exposure does not exceed the ADI and, where relevant, the acute dietary exposure does not exceed the acute RfD for a given chemical, the proposed MRLs will be recommended to the Australia New Zealand Food Standards Council (ANZFSC) for inclusion in the Food Standards Code and hence adoption into State and Territory food laws by reference. An exception is for antibiotics, where approval is also required from the TGA Working Party on Antibiotics. The risk assessment

process is summarised in Figure 2, with approximate time lines noted, where possible.

Where the estimated chronic dietary exposure exceeds the ADI, the following steps will be taken (Appendix 4):

1. The dietary exposure estimates should first be checked by both ANZFA and NRA and refined by including additional information where possible, to ensure all known factors have been accounted for and that the best use has been made of the available data.

2. If no relevant data are available, new data may need to be generated by the applicant for further assessment. The NRA will establish appropriate data requirements in order that these data are produced.

3. For existing chemicals already monitored in the ATDS, the dietary exposure estimates, based on residues in foods 'as consumed', as reported in the survey should be assessed by ANZFA and NRA. The sample size should be taken into account in assessing the uncertainty of an exposure estimate, based on these data. The NEDI based on STMR data is normally an overestimation because factors, such as processing factors or percentage crop treated for the chemical of interest may not be available.

   The potential for exceeding the ADI should be assessed by ANZFA and NRA, taking into account proposed extensions of use.

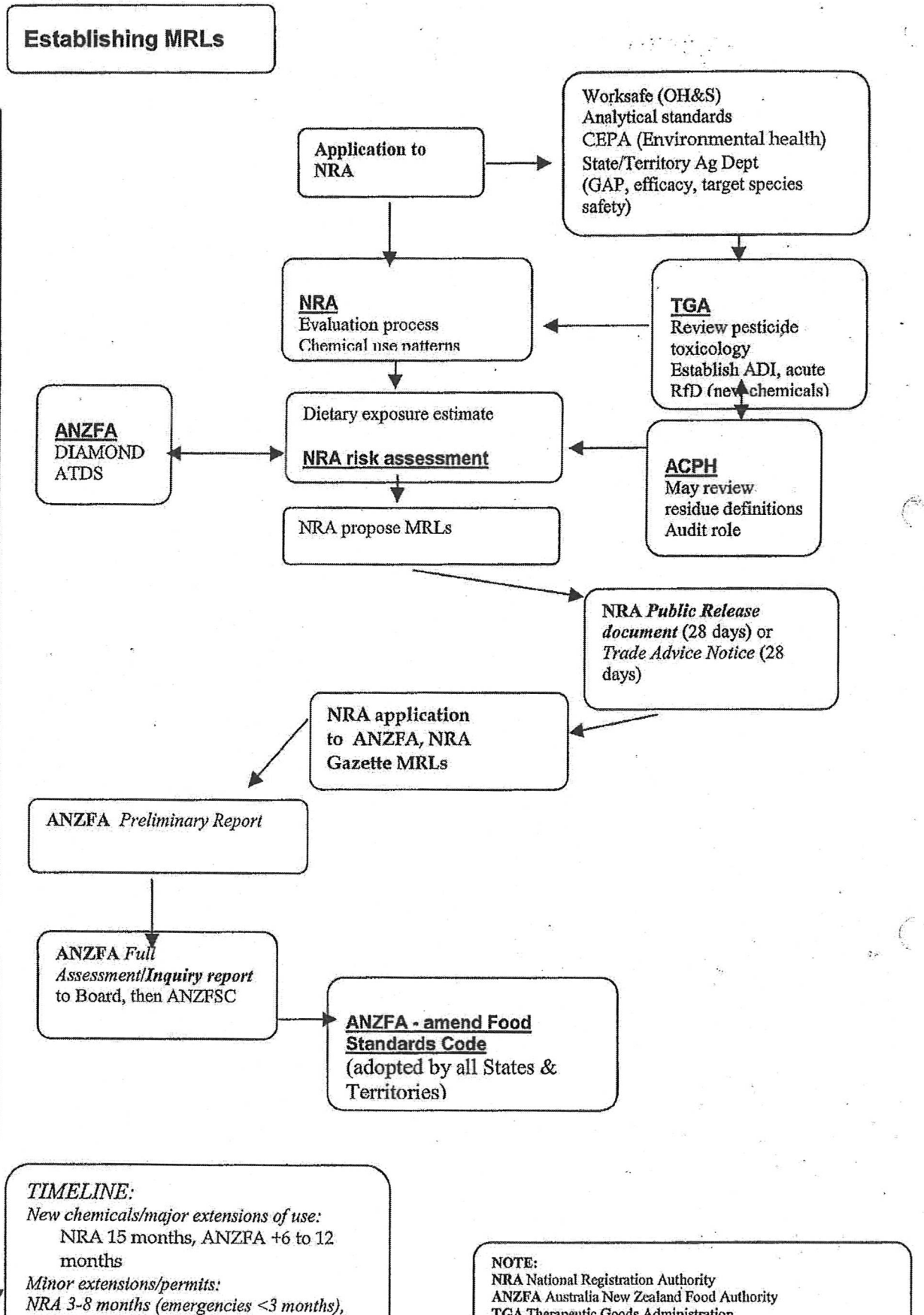
Where the estimated acute dietary exposure exceeds the acute RfD, the following steps will be taken (Appendix 5):

1. If the estimated acute dietary exposure exceeds the acute RfD, the dietary exposure estimates should first be checked by both ANZFA and NRA and refined by including additional information, where possible, to ensure all known factors have been accounted for and that the best use has been made of available data. If the estimated dietary exposure still exceeds the acute RfD; then

2. If no relevant data are available, new data may be generated by the applicant for further assessment, at the request of NRA.

3. NRA/TGA may review toxicology data and reference to target groups, if appropriate, to check if the acute RfD may be refined by additional data or a new study.

Where the refined chronic dietary exposure estimates exceed the ADI or, if applicable, refined acute dietary exposure estimates exceed the acute RfD for a given chemical, risk management options should be considered.


Establishing MRLs
Application to NRA
Worksafe (OH&S)
Analytical standards
CEPA (Environmental health)
State/Territory Ag Dept
(GAP, efficacy, target species safety)
NRA
Evaluation process
Chemical use patterns
TGA
Review pesticide toxicology
Establish ADI, acute RfD (new chemicals)
ANZFA
DIAMOND
ATDS
Dietary exposure estimate
NRA risk assessment
ACPH
May review residue definitions
Audit role
NRA propose MRLs
NRA Public Release document (28 days) or Trade Advice Notice (28 days)
NRA application to ANZFA, NRA Gazette MRLs
ANZFA Preliminary Report
ANZFA Full Assessment/Inquiry report to Board, then ANZFSC
ANZFA - amend Food Standards Code
(adopted by all States & Territories)
TIMELINE:
New chemicals/major extensions of use:
NRA 15 months, ANZFA +6 to 12 months
Minor extensions/permits:
NRA 3-8 months (emergencies <3 months), ANZFA +6 to 12 months
NOTE:
NRA National Registration Authority
ANZFA Australia New Zealand Food Authority
TGA Therapeutic Goods Administration
ACPH Australian Committee on Pesticides and Health
ANZFSC Australia New Zealand Food Standards Council

# 4. Risk management

If risk assessment procedures, including dietary exposure assessments, indicate a potential unacceptable risk to public health and safety due to the presence of a residue in food, different risk management options are available depending on the outcome of the risk assessment.

## 4.1 Chronic dietary exposure assessment

It is agreed that NRA is responsible for reviewing the use patterns of the chemical. It is agreed that the chronic dietary exposure estimate will be repeated with revised residue levels, if necessary, taking into account any additional data before final risk management decisions are taken. If additional data need to be generated, then a decision needs to be made as to whether or not risk management measures should be implemented whilst the data are being generated or not.

There are several risk management options available to NRA for new and existing chemicals, where the estimated dietary exposure exceeds the ADI, for example, extending the withholding period and modifying use patterns.

## 4.2 Acute dietary exposure assessments

It is agreed that the acute dietary exposure estimate will be repeated with revised residue levels provided by NRA, if necessary, taking into account any additional data before final risk management decisions are taken. In certain cases, further consideration of the toxicological data may be necessary. Risk management options are available if the estimated dietary exposure exceeds the acute Rfd, such as modifying use patterns.

## 4.3 NRA application to ANZFA

Where final exposure assessments indicate the ADI or acute RfD are not likely to be exceeded, then the revised uses for the chemical should be permitted and an application made to ANZFA proposing MRLs for inclusion in the Code.

Where final exposure assessments indicate there is potential for the ADI or acute RfD to be exceeded, under the revised and restricted patterns of use, then the use of the chemical will be reviewed by NRA.

Where final exposure assessments indicate the chronic dietary exposure is approximately equal to the ADI, the proposed uses of the chemical may be permitted but a recommendation made that ANZFA include the chemical in the Australia Total Diet Survey (ATDS) program for future monitoring.

## 5. References

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# Appendix 1: Definition of terms

## Health standards for pesticides and veterinary drugs

After toxicological evaluation each pesticide or veterinary drug is assigned an acceptable daily intake (ADI). For a chemical with potential for adverse effects on acute exposure, an acute reference dose (acute RfD) may also be determined.

*Acceptable daily intake (ADI)*

The acceptable daily intake (ADI) for humans is considered to be a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health (TGA 1997).

ADIs for pesticides and veterinary drugs are determined from available toxicological animal studies or from human data, by applying a safety factor to the no observable (adverse) effect level (NOEL) and refer to the level of exposure over a lifetime that is without appreciable risk to the consumer (mg/kg body weight/day). The NOEL is usually determined from animal toxicity studies and is the level at which no adverse effects have been observed. The most common safety factor is 100, which takes into account that humans may be ten times more sensitive than the experimental animals (inter-species differences) and that a proportion of the population may be ten times more sensitive than the average person (intra-species differences in susceptibility). The safety factor may be increased where the toxicity database is incomplete or decreased where there are human studies.

In Australia, the Therapeutic Goods Administration (TGA) sets ADIs for agricultural and veterinary chemicals.

*Acute reference dose (acute RfD)*

The establishment of an acute reference dose (acute RfD) for pesticide residues (mg/kg body weight/day) should be routinely considered, with reasons clearly identified where it has been decided not to set an acute RfD.

The 1995 Joint Meeting on Pesticide Residues (JMPR) Report suggests that an acute RfD should:

> *'reflect an analysis of the available data to establish a reference dose, analogous to the ADI, but relevant to acute exposure resulting from, for example, consumption of a single item or a*

*meal-sized portion of a commodity containing a pesticide residue'.*

Further guidance on the setting of acute RfDs is provided in the Report of the Intake Group Workshop, International Conference on Pesticides Variability and Acute Dietary Exposure Assessment, December 1998, York, UK.

The JMPR has established acute RfDs for a number of pesticides for use in risk assessment and will continue to establish acute RfDs at future meetings, where they are considered appropriate. In some cases, the estimation of acute RfDs may be based on different toxicological studies from those required to determine ADIs.

In Australia, TGA has responsibility for setting acute RfDs.

**Maximum residue limit (MRL)**

The maximum residue limit (MRL) is defined in Australia as the maximum concentration of a residue, resulting from the officially authorised safe use of a pesticide or veterinary drug, that is recommended to be legally permitted or recognised as acceptable in or on a food commodity (food, agricultural commodity or animal feed). The concentration is expressed in milligrams per kilogram of the commodity (or milligrams per litre of a liquid commodity). It is assumed that the chemical is used at the minimum effective dose and according to good agricultural practice (GAP).

Codex defines GAP for agricultural chemical use as (UNEP/FAO/WHO 1989):

*'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'.*

The Australian definition is:

*'The nationally recommended, authorised or registered use-pattern of chemicals, that is necessary for effective and reliable pest control under actual conditions at any stage of production, storage, transport, distribution and processing of food commodities and animal feed'*

A MRL is decided on the basis of the use pattern necessary to control the pest and is set to reinforce GAP and adherence to other label claims. If the use pattern leads to unacceptable residues in food, it should not be approved. It is not valid to set a lower MRL and leave the use pattern in place. It is also not viable to recommend a use pattern that fails to control the pest. The establishment of MRLs is necessary for commodities that are traded internationally and also serves to assure consumers that residues in food are as low as reasonably achievable and are safe.

**Extraneous residue limit (ERL)**

In Australia, extraneous residue limits (ERLs) are defined as:

> *'The maximum concentration of the pesticide residue that is recommended to be legally permitted or recognised as acceptable in or on a food, agricultural commodity or animal feed. The concentration is expressed in milligrams per kilogram of the commodity (or milligrams per litre of a liquid commodity)'.*

## Appendix 2: Residue data

### Residue definitions

Residue definitions are developed when assessing available residue, metabolism and toxicological data for the purposes of setting MRLs. In some cases, the definition used for the acute RfD may differ from that used for establishing ADIs, depending on the active metabolite that causes the observed adverse effect. Where appropriate, a separate residue definition may be developed for estimating dietary exposures, depending on the purpose of such assessments. The dietary exposure residue definition should include the parent chemical and relevant toxic metabolites and/or degradation products.

### New chemicals, extensions of use, review chemicals and permits

*Supervised trial median residue level (STMR)*

Supervised residue trials are designed to produce reliable data on residues occurring in food or feed commodities when use is at the maximum allowable conditions specified on the label and under normal commercial practice. The trial conditions, rate and number of applications etc are usually derived from efficacy studies, which demonstrate the lowest level of pesticide use necessary for pest control.

Where possible, the supervised trial median residue level (STMR) should be used in chronic dietary exposure assessments. STMRs are derived by the NRA, from residue data for the new chemical or for an existing chemical used on new commodities submitted by the applicant. Further guidance on the derivation of STMRs for products of animal origin when residues are transferred by feed items is provided in the 1997 FAO/WHO Joint Meeting on Pesticide Residues (JMPR) Report (FAO/WHO 1997, p 7-9).

Where the median residue level is at or below the limit of quantitation (LOQ) the STMR level should be established at the LOQ, except where other evidence suggests that the residue levels are essentially zero, according to JMPR procedure.

The amount of data on residue levels available for use in dietary exposure assessments is dependent on the commodity and specific residue. For pesticides, there may not be sufficient experimental data to determine the proportion of the crop or animal population treated, the STMR level, or to establish appropriate reduction or concentration factors. In this case, a single mean level may be used in dietary exposure models, derived from the raw

commodity data. However, if the supervised trial data are insufficient to estimate an STMR level, they will also be insufficient to establish an MRL. In some cases, there may not be any data on residue levels for a specific agricultural chemical used on a particular minor commodity. In these cases, NRA may be able to advise when data from another similar crop may be extrapolated.

*Modified Supervised trial median residue level (STMR-P)*

Supervised trials provide the basic residue data for chronic dietary exposure estimations, however, the residue level derived from trials may need to be adjusted because the commodity of trade used in the agricultural trials may not be the same as the portion which is eaten. STMRs should be based on the edible portion, where these data are available.

*Processing factors*

Processing factors take into account changes to pesticide residue levels in commodities due to storage, processing, preparation and cooking and are normally applied to the residue concentration levels in the raw or processed commodities in order to predict the residue level in the food as consumed.

For commodities that are processed and/or cooked, it is appropriate to apply mean reduction or concentration factors to the STMR or highest residue level (HR) established for the raw commodity to produce a residue level on the processed food for use in chronic and acute exposure estimates respectively, referred to as the STMR-P or HR-P. **The STMR-P residue level may only be used to estimate dietary exposure if the factor applies to the entire raw commodity.**

In Australia, processing factors for some commodities are available where processing trials have been undertaken. For example, there are sufficient data for selected agricultural chemicals 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.

*Fat soluble chemicals*

For pesticides or veterinary drugs 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 processing

factors. No universal distribution ratio is possible because the relative amount of residue partitioned into the fat varies with each chemical.

**Highest residue levels (HR)**

Highest residue (HR) levels are used in acute dietary exposure estimates and are derived from supervised trial data. In the composite sample with the highest value, it is assumed that the highest residue level reported from these samples is due to one commodity unit. For example, if there are 10 carrots in each composite sample, one carrot in that sample is assumed to contain the entire residue, the other 9 carrots assumed to contain no residue. This residue level (HL) may be modified by processing factors under certain conditions (HR-P).

**Variability factor (v)**

Variability factors may be derived from trial survey data if available for individual units of the commodity, for use in acute dietary exposure estimates. In the absence of such data, the variability factor is assumed to be the number of units required by sampling procedures in the composite sample in the supervised trial. For example, for carrots, if 10 units were required in each composite sample, the variability factor (v) would be 10. If residue trial data are available on individual crop units, then a variability factor can be derived directly from this data set.

**Existing chemicals**

Residue data for chemicals currently permitted for use on commodities as specified in Standard A14 - Maximum Residue Limits of the Australian Food Standards Code may be derived from a variety of sources available to NRA and ANZFA. Such data may be required to construct a model to assess the impact on estimated dietary exposure of extending the use of an existing chemical or for the Existing Chemical Review Program.

***Total diet surveys***

The Australian Total Diet Survey (ATDS), formerly known as the Australian Market Basket Survey (AMBS) (ANZFA 1996, 1998) provides information on the levels of pesticide and veterinary drug residues in a wide range of Australian foods, prepared as consumed. The mean concentration of residues in composite samples is reported.

In many cases, particularly for prepared or processed foods, the ATDS is the major source of information on the level of residues in these foods because foods are analysed as consumed rather than as raw commodities.

*Government surveillance data*

The National Residue Survey (NRS), conducted on a regular basis by the department of Agriculture, Fisheries and Forestry-Australia (AFFA), 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.

State government primary industries/agriculture departments also conduct regular surveillance programs of specific commodities, or specific agricultural or veterinary chemical residues, both as random surveillance programs for compliance purposes and for surveying specific commodities and/or locations when a problem is suspected. State data may be used to compile a national overview of the level of agricultural and veterinary chemical residues in food. State government health departments may also undertake surveys of specific foods.

In compiling data from several sources the sampling procedures, analytical methods and limit of quantitation reported need to be considered.

*Sampling procedures for food commodities in trade*

Australia has developed procedures for conducting residue trials and measurement of residue levels in commodities. These procedures are published (NRA 1993) and in general agreement with those of FAO (FAO 1986).

*Limit of Analytical Quantitation (LOQ)*

Standardising use of the term 'Limit of Analytical Quantitation' (LOQ) and assignment of values to samples with no detectable residues is crucial to enable the comparison of residue data from different sources. The LOQ is the same as the Limit of Determination. The use of standardised procedures for the reporting of samples with no detectable residues was recommended by the 1996 JMPR FAO panel informal workshop, such that where all residue trials data are < LOQ, the STMR level would be assumed to be at the LOQ, unless there was scientific evidence that residues were 'essentially' zero. In the case of trials using different LOQs, the STMR level would normally be based on the lowest LOQ (JMPR 1998).

**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. These residues are usually considered as contaminants. Some reduction in food residues can be achieved by identifying sources of environmental contamination and adopting practices to avoid exposure as far as possible.

Residue data for dietary exposure estimates are derived from survey data, as for existing chemicals.

# Appendix 3: Food consumption data

## Chronic dietary exposure assessments

The risk assessment model requires an estimate of chronic food chemical dietary exposure. The mean consumption of commodities for all respondents (whole population) is integrated with residue data for those commodities (STMR or survey data).

### National dietary survey data

Food consumption data for all respondents aged 2 years and over (mean level of consumption) are derived for each commodity from the 1995 National Nutrition survey (NNS) using the ANZFA DIAMOND computer program. In the 1995 NNS food consumption data were reported for 13 858 respondents for the preceding 24 hours (24-hour recall method). The survey was conducted over a 12-month period, with a representative sample of the Australian population.

Food consumption data for each commodity includes all uses of the raw commodity, for example 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).

The DIAMOND program derives food consumption data for raw commodities from individual dietary records in the 1995 NNS, by applying recipes to mixed foods to enable the proportional weight of raw ingredients in these foods to be included in the total amount of the raw commodity consumed by each individual. Residue concentration levels are assigned to total raw commodity consumption levels for each individual in the survey and their individual dietary exposure estimated, adjusted for their own bodyweight. Mean population statistics are then derived from the estimates of individual's dietary exposure to the residue.

s

The DIAMOND program is based on the commodity classification used in Food Standard A14, which corresponds to that used in Codex standards.

## Acute dietary exposure assessments

The risk assessment model requires an estimate of acute food chemical dietary exposure.

**Large portion sizes**

A high consumption (97.5th percentile, consumers of the food only) of a single raw food for a single eating occasion (or over 24 hours depending on the chemical) is integrated with the highest residue expected in the edible portion of a single serving (HR or HR-P), which may be the MRL level of agricultural and veterinary chemical residue.

Food consumption data for high consumers are derived from the 1995 NNS using the ANZFA DIAMOND program (Figure 1). If a target group has been identified by TGA for the acute RfD, food consumption data are derived for this population group. In general, only food eaten as a raw commodity would be included in the data set. For example, for an acute dietary exposure for a chemical residue on apples, food consumption data for people consuming raw apples only would be used; data for consumption of apples used in processed or cooked food or for apple juice would not be included.

**Unit commodity weights**

Unit commodity weight data are required for NESTI calculations, where the number of commodity units per large portion size is 3 or less. Table 1 provides a preliminary list of fruit and vegetables in this category. Median unit commodity weights may be derived by NRA from residue variability trials where individual commodity units were analysed separately, but not from trials using composite samples. Such data are not currently available in Australia, but ANZFA and NRA are in the process of developing an Australian database.

If it is not possible to derive median unit weights for a commodity, other reference documents may be used by ANZFA to determine the mean weight of a medium sized unit of that commodity, for example:

- Composition of Foods, Australia (COFA) volumes 1-7, ANZFA, AGPS, Canberra
- 1995 NNS unit weights (selected commodities only) available from technical support files (unpublished); or
- Ministry of Agriculture, Fisheries and Food 1993. Food portion sizes, HMSO, UK.

**Figure 1: Derivation of large portion size data**

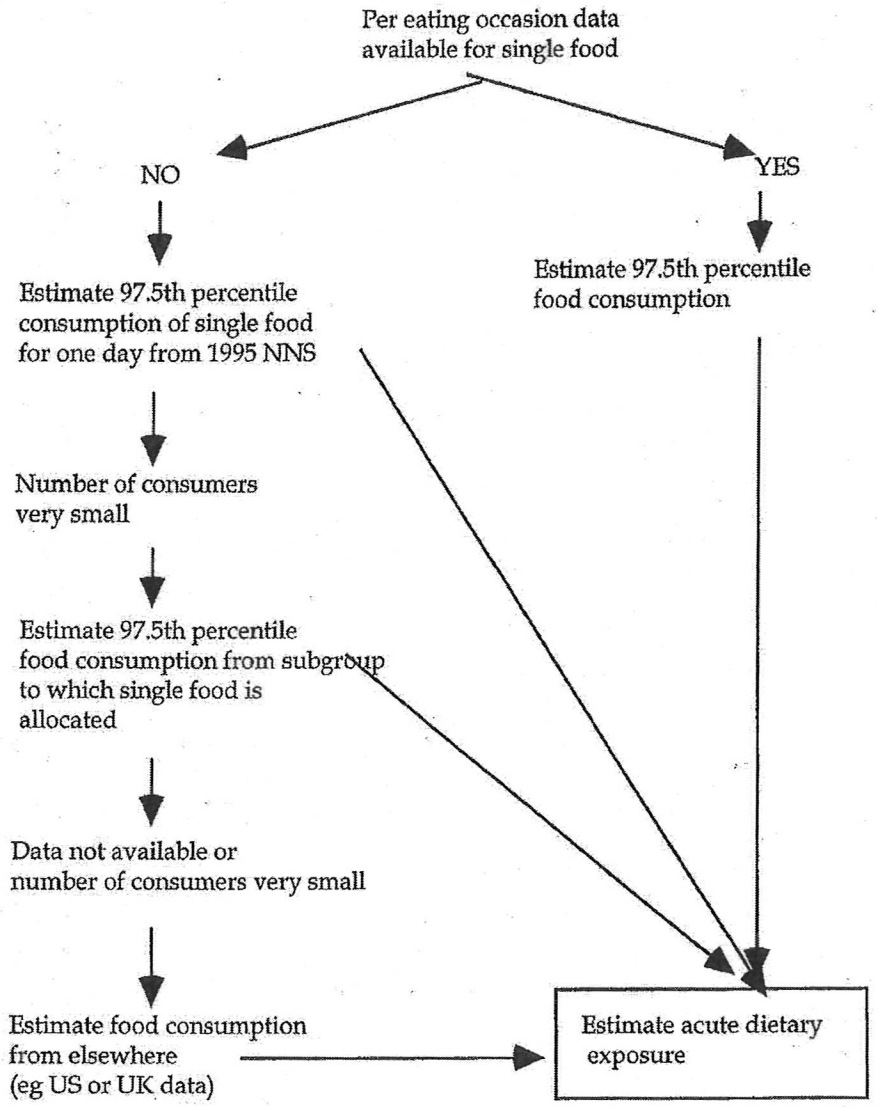


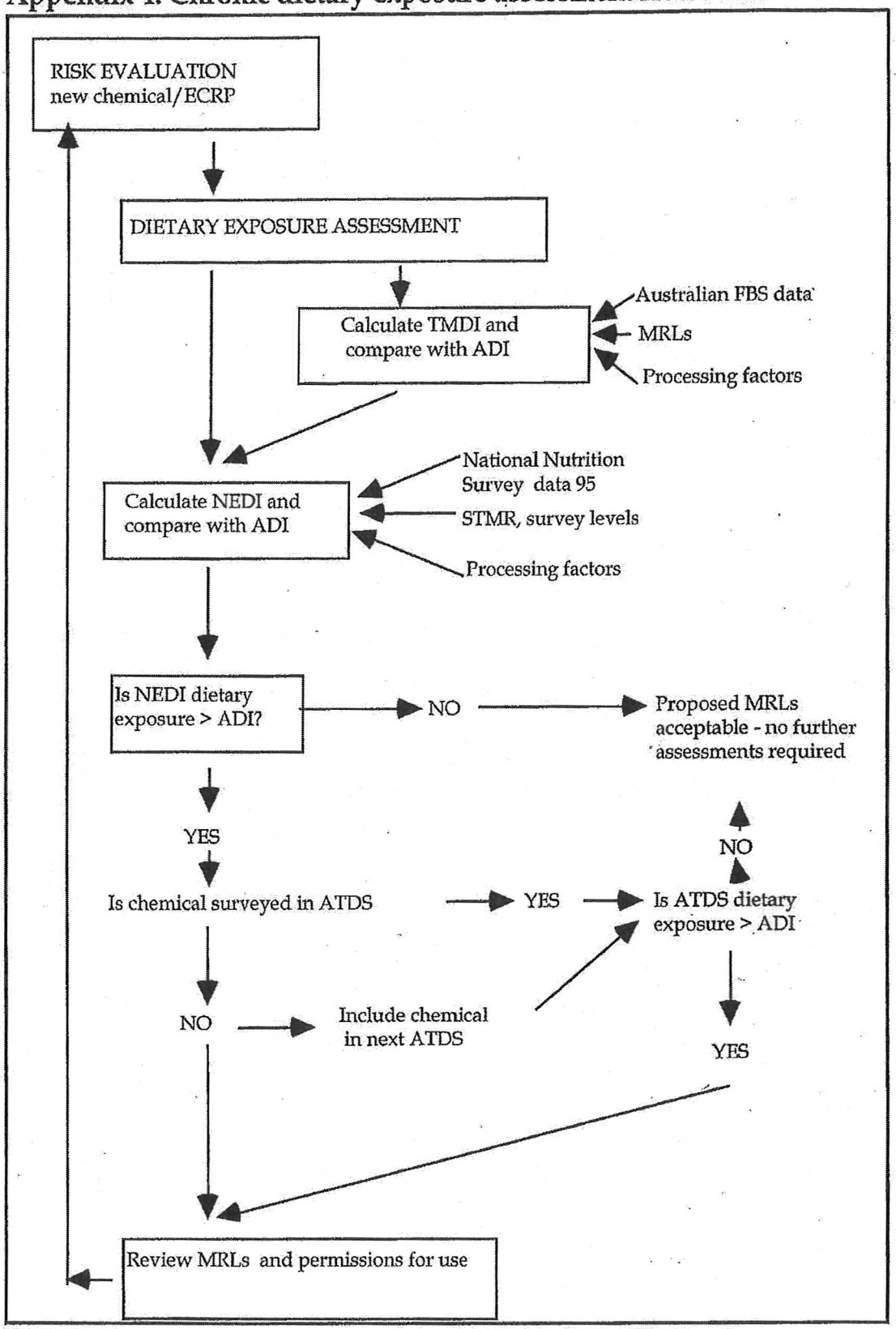
**Table 1: Preliminary list of commodities with 3 or less commodity units that may comprise a large portion**

The commodities listed below are those for which the variability coefficient (v) should be used in calculating the NESTI if no residue data are available on an individual commodity basis. This list represents the major examples but should not be considered exhaustive.

| Commodity list | Pawpaw/ Papaya | Cucurbits |
|---|---|---|
| | Pineapple* | Cucumber* |
| Citrus fruit | | Courgette/ Zucchini |
| Grapefruit | Root and tuber vegetables | Melon* |
| Lemon* | Beetroot | Watermelon* |
| Mandarin and other soft citrus | Carrot | Marrow* |
| Orange | Celeriac* | Pumpkin* |
| Lime* | Jerusalem artichoke | |
| | Potato | Brassica |
| Pome fruit | Parsnip | Broccoli |
| Apple | Swede* | Cauliflower* |
| Pear | Sweet potato | Cabbage* |
| Quince | Turnip* | Chinese cabbage* |
| | Yam | Kohlrabi |
| Stone fruit | | |
| Apricot | Bulb and stem vegetables | Lettuce and leaf vegetables |
| Peach | Onion | Lettuce* |
| Plum | Fennel bulb | Spinach |
| Nectarine | | Chicory/Witloof |
| | Fruiting vegetables | |
| Berries | Tomato | Stem vegetables |
| Table grape (bunches). | Pepper, sweet | Asparagus |
| | Pepper, Chilli | Celery |
| Miscellaneous fruit | Aubergine* | Globe artichoke |
| Avocado | | Leek |
| Banana | | Rhubarb |
| Fig | | |
| Guava | | |
| Kiwi fruit | | |
| Mango | | |

* A single portion of these commodities usually consists of less than one unit. Consideration should be given to generating variability data for grapes on an individual bunch basis since the variation in residue levels between different bunches is likely to be high compared with the variation of residues between the individual grapes within a bunch.

## Appendix 4: Chronic dietary exposure assessment flowchart



# Appendix 5: Acute dietary exposure assessment flowchart