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**[26–16]**

## **Supporting Document 1 (at Approval)**

The risk assessment approach to establishing *All other foods except animal food commodities* MRLs – Proposal P1027

Managing Low-level Ag & Vet Chemicals without MRLs

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### **Executive Summary**

This supporting document provides information relating to the development of an approach to establish *All other foods except animal food commodities* MRLs for agricultural and veterinary chemicals (agvet) set out in Schedule 20 in the *Australia New Zealand Food Standards Code* (the Code). This pilot approach was undertaken with a small number of chemicals already listed in the Code with the aim of developing principles and criteria to establish for specific agvet chemicals, *All other foods except animal food commodities* MRLs that are high enough to allow for inadvertent presence of the chemical in food but are low enough to limit the potential for 'off label' use of the chemical. The approach is consistent with the Australian Pesticides and Veterinary Medicines Authority's (APVMA's) risk assessment framework for approving and registering agvet chemical products, and with the risk assessment approach for establishing MRLs in the Code.

The consultation paper released in late 2014 indicated FSANZ proposed to call the MRL category for addressing the presence of low level inadvertent agvet chemical residues in food commodities *All other foods* MRL.

In piloting the approach it was determined that for animal food commodities, if regard is given to existing animal commodity MRLs the outcome may be an *All other foods* MRL that is too low to allow for inadvertent presence of pesticide residues in a plant commodity. However, if *All other foods* MRLs are set on the basis of comparatively higher plant commodity MRLs, permissions for animal food commodities captured in *All other foods* MRLs could be higher than those that exist for animal food commodities with established MRLs. To resolve this issue, animal food commodities are categorically excluded from the initially proposed descriptor of the MRL category and the descriptor modified to *All other foods except animal food commodities*.

Approximately 500 agvet chemicals, including herbicides, fungicides, insecticides and veterinary drugs are currently regulated under Schedule 20. For the purposes of the pilot, FSANZ developed a two-stage process to identify a manageable sub-set of chemicals in the Code for which an *All other food except animal food commodities* MRL could be specifically assessed on a case-by-case basis. An initial list of 132 agvet chemicals was selected from the Australian Government Department of Agriculture and Water Resources imported food inspection data, together with those suggested by stakeholders such as the APVMA and State-based enforcement agencies.

This list was reduced to 19, for a case-by-case consideration in the second stage.

In Stage 2, a number of principles were developed, in consultation with the APVMA, to guide setting an *All other foods except animal food commodities* MRL for each chemical. These principles ensured that a consistent approach was used and that chemicals of concern would be excluded from consideration. Generally, a proposed *All other foods except animal food commodities* MRL should be higher than the limit of detection to allow for the inadvertent presence of the agvet chemical in other foods. However, the magnitude of existing MRL permissions was considered and the proposed *All other foods except animal food commodities* MRLs are low enough to discourage off-label use of the agvet chemicals.

An individual dietary exposure assessment (DEA) based on internationally agreed methodologies was undertaken for each chemical, which took into consideration current estimates of dietary exposure from risk assessments relating to existing MRL permissions, as well as a conservative 'worst case' assessment of potential contribution to dietary exposure from *All other foods except animal food commodities*. Both chronic and, where appropriate, acute dietary exposures were considered. Health based guidance values (HBGVs<sup>1</sup>) used in the DEAs were those listed on the web pages of the Australian Government's Office of Chemical Safety (OCS) or Food and Agricultural Organization/World Health Organization's (FAO/WHO) Joint Meeting of Pesticide Residues (JMPR). Overall, an agreed criterion was that the *All other foods except animal food commodities* MRL should be low enough that the contribution from commodities included to estimate the total chronic dietary exposure would not exceed approximately 20% at the time the MRL was proposed. This was to ensure that future establishment of specific commodity MRLs for a chemical does not result in estimates of dietary exposure exceeding relevant HBGVs.

At the completion of the Stage 2 assessment process, *All other foods except animal food commodities* MRLs were proposed for these chemicals: 2-phenylphenol, ametoctradin, azoxystrobin, bifenthrin, captan, cyfluthrin, deltamethrin, fenhexamid, fludioxonil, glyphosate, iprodione, methomyl, thiodicarb, penthiopyrad, pyrimethanil, spinosad, thiabendazole, triadimefon and triadimenol.

On completing the application of this pilot approach to the selected agvet chemicals, the outcomes were reviewed as were the principles and processes developed in Stage 2 to establish the *All other foods except animal food commodities* MRLs. The proposed revised principles and processes would provide a consistent approach to review agvet chemicals listed in Schedule 20 with the aim of establishing *All other foods except animal food commodities* MRLs for additional agvet chemicals over time, on a case-by-case basis. This process would also take into consideration ongoing amendments to Schedule 20 proposed or considered by the APVMA and from FSANZ's annual MRL harmonisation process.

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<sup>1</sup> HBGVs include the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD). See Glossary for definition of ADI and ARfD.

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# Glossary

ADI	<i>Acceptable Daily Intake.</i> The amount of a chemical that can be consumed every day of life without appreciable risk to health, expressed in mg/kg body weight.
ARfD	<i>Acute Reference Dose.</i> The amount of a chemical that can be consumed in a short period of time, usually over one meal or one day, without appreciable risk to health, expressed in mg/kg body weight.
bw	<i>The mean body weight (kg)</i> of all respondents in the population group.
ERL	<i>Extraneous Residue Limit</i> means the maximum level of a residue of a chemical permitted to be present in a food and which arises from environmental sources other than the use of a chemical directly or indirectly on the food.
GAP	<i>Good Agricultural Practice.</i> The application of a chemical according to label instructions.
HR	<i>The Highest Residue (mg/kg)</i> from a supervised trial that results from using the chemical according to the label directions. The MRL is usually set based on this figure.
HR-P	<i>Highest residue - Processed.</i> Highest residue (mg/kg) in the processed commodity, calculated by multiplying the HR in the raw commodity by the processing factor.
LOD	<i>Limit of Determination</i> - the lowest quantity or concentration of residue that can be determined.
LOQ	<i>Limit of Quantification</i> – the lowest concentration at which the analyte cannot be reliably measured by an analytical method but at which some predefined goals for bias and imprecision are met. The LOQ may be equivalent to the LOD or it could be at a much higher concentration.
LOR	<i>Limit of Reporting</i> - the smallest concentration (or amount) of analyte that can be reported by a laboratory
LP	Highest <i>Large Portion</i> provided (97.5 <sup>th</sup> percentile of consumption for consumers of the commodity), in kg of food per day.
MRL	<i>Maximum Residue Limit.</i> The maximum residue of a chemical permitted in food.
NEDI	<i>National Estimate of Dietary Intake.</i> A dietary exposure assessment calculated across the population for all foods with an MRL and related commodities. It determines long term (chronic) exposure across a lifetime. Exposures are calculated for each food using consumption data at the mean for all respondents and summed across all foods to determine an exposure from all foods with MRLs. The summed dietary exposure assessment is compared to the ADI in order to determine whether estimated total dietary exposures are likely to be a risk to public health and safety.
NESTI	<i>National Estimate of Short Term Intake.</i> A dietary exposure assessment calculated for high consumers for all foods individually that have an MRL and related commodities. It determines short term exposure over one meal or one day. Exposures are calculated for each food separately using consumption data at the 97.5 <sup>th</sup> percentile for consumers of the food only and IS NOT summed across all foods. The estimated dietary exposure is compared to the ARfD in order to determine whether estimated dietary exposures are likely to be a risk to public health and safety.
PF	<i>Processing Factor.</i> A numerical factor that can be applied to an MRL to represent the change in concentration of a chemical due to the food being processed. For example, the residues in orange juice have a factor of 0.8 of the MRL for oranges, or the residues in sultanas is 1.2 the MRL of the residues in grapes.
STMR	<i>Supervised Trial Median Residue.</i> The median concentration of a chemical in mg/kg from a number of analyses of residues in the food following application of the chemical according to the label directions.
STMR-P	<i>Supervised Trial Median Residue</i> in the processed commodity, in mg/kg
U	<i>Unit Weight</i> edible portion of the commodity, in kg of food per day.
v	The <i>variability factor</i> represents the range of variability in residues in the individual units within the composite samples that have been analysed.

# 1 Introduction

## 1.1 Maximum residue limits

Standard 1.4.2 and Schedules 20–21 in the *Australia New Zealand Food Standards Code* (the Code) set out the maximum residue limits (MRLs) and extraneous residue limits (ERLs) for agricultural or veterinary chemicals that are permitted in foods for sale in Australia.

### 1.1.1 All other foods except animal food commodities MRLs

For the purpose of this Proposal, *All other foods except animal food commodities* MRL means all foods except for animal food commodities for which an MRL has not been established, or is not currently being established for a specific agvet chemical. This would result in the *All other foods except animal food commodities* MRL for each agvet chemical being applicable to foods other than the raw or primary agricultural commodities.

The APVMA sets MRLs in animal food commodities to control the use of veterinary drugs. In addition, in some cases the APVMA has set specific MRLs for animal products where a plant commodity is treated according to registered directions but trace levels of residues might be present in animal food commodities even if good agricultural practice (GAP) is adhered to. In both cases, the MRLs between plant and animal food commodities may vary by orders of magnitude.

For animal food commodities, if regard is given to existing animal food commodity MRLs, and the initially proposed term of *All other foods* MRL is set at that level, the outcome may be an *All other foods* MRL that is too low to allow for inadvertent presence of pesticide residues in a plant commodity. However, if the *All other foods* MRLs are set on the basis of comparatively higher plant commodity MRLs, the permission for animal food commodities captured in *All other foods* could be higher than those that exist for animal food commodities with established MRLs. To resolve this issue, animal food commodities have been excluded from and the descriptor used throughout this document for this MRL category is, *All other foods except animal food commodities* MRLs.

## 2 Approach

FSANZ developed a two stage process (Table 1) to identify suitable agvet chemicals to evaluate the proposed *All other foods except animal food commodities* MRL approach. A screening process, Stage 1, was used to derive a list of agvet chemicals that could be used to pilot the Proposal P1027 approach (initial list of 132 chemicals short-listed to 19 chemicals for consideration, see Section 3). The list of chemicals generated was then used to consider establishing *All other foods except animal food commodities* MRLs on a case-by-case basis for each agvet chemical in Stage 2 (see Section 4).

This Proposal sets out the principles, approaches and procedures for the ongoing establishment of *All other foods except animal food commodities* MRLs for agvet chemicals listed in the Code as part of FSANZ's routine MRL evaluation processes, which incorporates the findings from a review of the pilot (Stage 1) outcomes.

**Table 1: Stages for proposing *All other foods except animal food commodities* MRLs**

Stage	Description	Purpose	Process	Inputs	Outputs
1	Screening	Obtain a list of agvet chemicals to pilot new process for setting <i>All other foods except animal food commodities</i> MRL	Administrative inputs used to derive a suitable list of agvet chemicals to pilot in Stage 2	<ul style="list-style-type: none"> <li>Assumptions</li> <li>Analytical limits</li> <li>Existing permissions</li> <li>Available HBGV</li> <li>Food consumption data</li> </ul>	Lists of: <ul style="list-style-type: none"> <li>Agvet chemicals excluded from Stage 2</li> <li>Agvet chemicals included in Stage 2</li> </ul>
2	Proposing <i>all other foods except animal food commodities</i> MRLs	Determine appropriate <i>All other foods except animal food commodities</i> MRL on a case by case basis	Scientific inputs used to calculate estimated dietary exposure	<ul style="list-style-type: none"> <li>List from Stage 1</li> <li>Up to date existing MRL permissions</li> <li>Additional data on analytical limits</li> <li>HBGV</li> <li>Refined food consumption data</li> </ul>	<ul style="list-style-type: none"> <li>Dietary exposure estimates incorporating current permissions and <i>All other foods except animal food commodities</i> for each agvet chemical</li> <li>Proposed MRL for <i>All other foods except animal food commodities</i></li> </ul>

### **3 Stage 1: Screening of chemicals to establish the risk assessment approach for *All other foods except animal food commodities* MRLs**

There are approximately 500 agvet chemicals currently listed in Schedules 20 and 21 of the Code. Using all of these in the P1027 approach was considered impractical and therefore a smaller list of agvet chemicals was identified for this Proposal.

FSANZ and the APVMA agreed that a useful starting point for P1027 was the list of agvet chemicals identified in the Department of Agriculture and Water Resources imported food chemical analytical screen, the chemicals the APVMA considered appropriate for possible inclusion in P1027 and the list of chemicals nominated by stakeholders following a request in the first P1027 consultation paper released in late 2014. A list of 132 agvet chemicals was subsequently generated for consideration in the Stage 1 screening process (Appendices A3 and A4).

In Stage 1, this initial list was refined using a number of [exclusion criteria](#) for the first call for submissions<sup>2</sup> based on the type of chemical, data on analytical limits, existing permissions, established HBGVs and Australian food consumption data. A screening MRL for *All other foods except animal food commodities* was used in this process, the value assigned was two times the analytical limit of reporting or quantification (LOR/LOQ) for that chemical residue of interest. The outcome of the screening process was to either include or exclude chemicals from Stage 2 i.e. only chemicals that passed the Stage 1 screening were considered for establishing *All other food except animal food commodities* MRLs in this Proposal. Chemicals that did not pass Stage 1 may be assessed in a future proposal as their exclusion may have been due to lack of appropriate data and not necessarily for safety reasons. Conversely, chemicals considered as suitable at this stage may not necessarily end up with an *All other foods except animal food commodities* MRL when considered as an individual case in Stage 2.

### 3.1 Exclusion criteria

For preliminary screening of agvet chemicals at Stage 1 the following exclusion criteria were developed based on FSANZ and APVMA expert opinion:

- Agvet chemical is not currently listed in Schedule 20
- Agvet chemical is not registered for use in Australia
- Agvet chemical is listed only in Schedule 7 of the Poisons Standard (the SUSMP) of the Therapeutic Goods Administration
- Agvet chemical is a veterinary medicine
- Agvet chemical has an ERL<sup>3</sup> listed in Schedule 21
- Agvet chemical is currently nominated by the APVMA for formal review
- Based on current MRL permissions, the most recent FSANZ/APVMA national estimate of dietary intake (NEDI) (i.e. chronic dietary exposure estimate), from residues of the agvet chemical exceeded 80% of the relevant HBGV, the Acceptable Daily Intake (ADI)
- The national estimate of short term intake (NESTI) (i.e. acute dietary exposure estimate) exceeded the acute reference dose (ARfD), using a 'worst case' commodity consumption amount and the screening MRL for *All other foods except animal food commodities*
- Based on the screening MRL, the percentage contribution of *All other foods except animal food commodities* was calculated to be greater than 20% of the estimated total chronic dietary exposure.

### 3.2 Existing permissions

Only agvet chemicals with existing MRL permissions in the Code were considered during the screening process. Existing MRLs for the specific agvet chemicals and the relevant commodities were used in the screening calculations. During the screening and subsequent dietary exposure assessment process (December 2014–March 2016), the APVMA may have made amendments to Schedule 20 as permitted under the *Food Standards Australia New Zealand Act, (1991)* and in line with existing MRL processes. Where an amendment was proposed for an agvet chemical under consideration in Proposal P1027, the APVMA amendments to Schedule 20 were considered in the *All other foods except animal food commodities* MRL setting process.

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<sup>2</sup> <http://www.foodstandards.gov.au/code/proposals/Pages/P1027.aspx>

<sup>3</sup> extraneous residue limit (ERL) means the maximum level of a residue of a chemical:

(a) permitted to be present in a food; and

(b) arises from environmental sources other than the use of a chemical directly or indirectly on the food.

Similarly, where an amendment was proposed in Proposal M1011 (MRL harmonisation requests for 2015) for an agvet chemical under consideration in P1027, this amendment was also considered in the screening and subsequent dietary exposure assessment process.

### 3.3 Health-based guidance values

HBGVs were sourced from the Office of Chemical Safety where possible. However, since the establishment of ARfD values only became routine practice for the OCS in 2000 there are many older agvet chemicals for which no ARfD exists. In such cases the HBGVs listed in the evaluations of pesticides performed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) were used. If no HBGV was available the agvet chemical was excluded from progressing to Stage 2. Where an HBGV was available this was used together with existing permissions, consumption data and analytical limits to produce a screening estimate of dietary exposure as a %HBGV to assist with establishing which agvet chemicals should be considered in Stage 2.

### 3.4 Food consumption data

Food consumption data used for both Stage 1 and Stage 2 were derived from the 1995 Australian National Nutrition Survey (1995 NNS) and the 2007 Australian National Children's Nutrition and Physical Activity Survey (2007 ANCNPAS). The design of these two surveys varied somewhat and key attributes of each are set out in Appendix A5. Mean total food consumption was derived for the entire population aged 2 years and above, and used as the basis for initial chronic dietary exposure estimates. A 'worst case' commodity high consumption amount (97.5<sup>th</sup> percentile for consumers of the commodity) was derived for the population aged 2 years and above, and for children aged 2–6 years for use in the initial acute dietary exposure estimates.

## 4 Stage 2: Establishing *All other foods except animal food commodities* MRLs on a case-by-case basis

### 4.1 Principles

In consultation with the APVMA, FSANZ developed a number of principles to assist in determining a consistent, appropriate and scientifically robust approach that supported good agricultural practice. The *All other foods except animal food commodities* MRLs proposed are underpinned by a [dietary exposure assessment](#) (DEA)<sup>4</sup> of the estimated chronic, and where appropriate short term (acute) dietary exposure to the agvet chemical residue from existing established specific commodity and proposed *All other foods except animal food commodities* MRLs. DEAs were undertaken to confirm if estimated exposures were less than the relevant HBGVs for the agvet chemical residue and are protective of the health and safety of the Australian population.

The establishment of the proposed *All other foods except animal food commodities* MRLs for each agvet chemical followed these principles:

- animal food commodities are excluded from the proposed *All other foods except animal food commodities* MRL

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<sup>4</sup> <http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureand4438.aspx>



- incorporates *Supervised Trial Median Residue* (STMR) data when available or otherwise existing commodity MRLs in the estimated DEA.
- the percentage contribution of *All other foods except animal food commodities* to estimated total chronic dietary exposure is less than 20% at the time of proposing the MRL.
- default values may not be adopted
- needs to allow for inadvertent presence of the agvet chemical residues in a food commodity
- needs to minimise potential off-label use

#### **4.2 Lowest concentration at which an *All other foods except animal food commodities* MRL can be set**

When proposing an *All other foods except animal food commodities* MRL the magnitude of existing commodity MRLs was taken into consideration. The *All other foods except animal food commodities* MRL should also be low enough to prevent off label use and high enough to allow for inadvertent presence of the agvet chemical. A range of agvet chemicals currently have existing plant and/or animal commodity MRLs set at the Limit of Determination<sup>5</sup>. The Limits of Determination for animal food commodities are not relevant because these commodities are exempted from *All other foods except animal food commodities* MRLs. While the Limit of Determination is the lowest MRL at which an *All other foods except animal food commodities* MRL can be set, it may not be desirable to do so as it may not be high enough to allow for inadvertent presence of the chemical in the food. Therefore, the range of MRLs, the number of commodities with current MRLs and the contribution of *All other foods except animal food commodities* to the estimated total dietary exposure were all considered in establishing an *All other foods except animal food commodities* MRL that is higher than the Limit of Determination.

#### **4.3 Contribution to total dietary exposure from *All other foods except animal food commodities***

One of the criteria applied in Stage 2 of the pilot was that the percentage contribution of *All other foods except animal food commodities* to estimated total chronic dietary exposure cannot not be greater than 20% at the time of proposing the *All other foods except animal food commodities* MRL (the '80/20 principle', see Figure 1). This was to ensure that future establishment of specific commodity MRLs for a chemical do not result in estimates of dietary exposure exceeding relevant HBGVs. It also provides an indication that the proposed *All other foods except animal food commodities* MRL was low enough to minimise off-label use of the pesticide, while allowing for the inadvertent presence of a residue that may occur from use of a pesticide in accordance with the approved label directions and registered uses (as specified by the APVMA).

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<sup>5</sup> An asterisk '\*' appearing in Schedules 20 or 21 denotes that the maximum residue limit or the extraneous residue limit is set at or about the *limit of determination*.

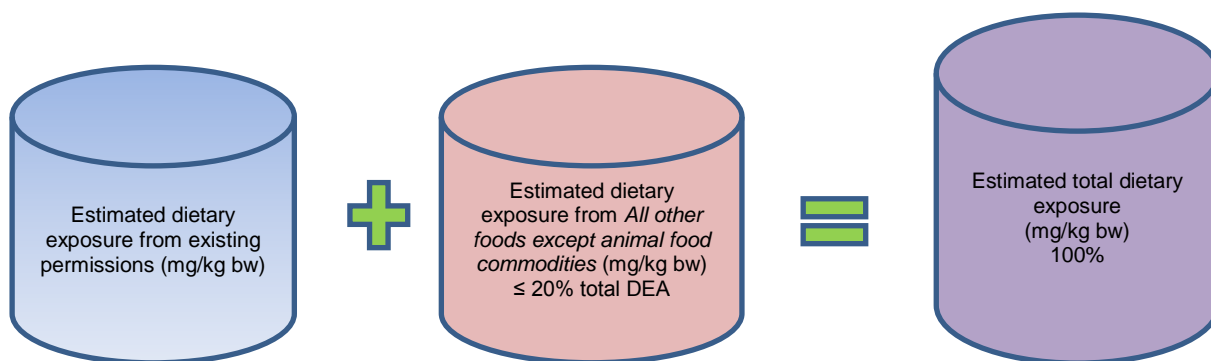


Figure 1: Percentage contributions of All other foods except animal food commodities to total

#### 4.4 Estimating dietary exposure

The APVMA and FSANZ undertake DEAs for all agvet chemicals using [internationally recognised methodologies](#)<sup>6</sup>. The DEAs undertaken for this proposal have followed these same methods. Dietary exposure is calculated as follows:



In order to conduct a dietary exposure assessment, a food consumption amount is required on a gram per kilo body weight per day (g/kg bw/day) basis for all the food commodities that do not have specific MRLs. To determine this, an estimate of the mean food consumption per person for the entire Australian population was calculated using the 1995 NNS data or the 2007 ANCNPAS survey adjusted for individual body weights as appropriate.

Further information on [dietary exposure assessments](#)<sup>7</sup> is available on the FSANZ website.

#### 4.5 Chronic dietary exposure assessment

In conducting chronic (NEDI) DEAs, FSANZ considered the residues in foods that could result from the permitted uses of an agvet chemical product. Median chemical residue concentration data from standardised trials (STMR or STMR-P if adjusted for processing factors) were used if available for existing commodities listed in Schedule 20, instead of the MRL, as these data provide a more realistic estimate of dietary exposure. DEAs based on MRL data result in an overestimate of exposure as the assessment assumes that all food with an applicable commodity MRL contain the residue at the specified concentration.

The proposed MRL for *All other foods except animal food commodities* was used in the NEDI calculations. The use of the *All other foods except animal food commodities* MRL in dietary exposure estimates will result in considerable overestimates of exposure from this group of foods because the assessment assumes that the chemical is present at the specified level in all commodities for which there is no current registered use. This is a 'worse-case' scenario in the case of an *All other foods except animal food commodities* MRL because the foods captured are not actively treated with the chemical of interest.

<sup>6</sup> [http://www.inchem.org/documents/ehc/ehc/ehc240\\_index.htm](http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm) (Chapter 2)

<sup>7</sup> <http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureandin4438.aspx>

The residues that were assumed to occur in all other foods except animal food commodities were multiplied by the daily consumption of these foods derived from individual dietary records from the 1995 and 2007 NNS for all survey respondents. These calculations take into account the consumption of foods as ingredients in processed foods e.g. *apple* in *apple pie* and *wheat* from *flour* in *bread*.

The mean total food consumption for the Australian population aged 2 years and above was estimated at 51 g/kg bw/day (1995 NNS). The difference between 51 g/kg bw/day and the sum of consumption of commodities with existing permissions was used as the consumption amount in the DEA for *All other foods except animal food commodities* (see Figure 2). If MRLs did not exist for all animal food commodities, the consumption amount for the animal food commodities that did not have MRLs was subtracted from the total consumption amount to be used for the *All other foods except animal food commodities* group.

$$\begin{aligned} \text{Total dietary exposure (mg/kg bw/day)} &= \\ &\text{Exposure from commodities with existing MRL permissions} \\ &+ \text{Exposure from } \textit{All other foods except animal food commodities} \\ \text{Where:} \\ \text{Exposure from commodities with existing MRL permissions} &= \\ \text{Food consumption for existing commodities with MRLs} & \\ \quad \times \text{existing pesticide residue concentration data (MRL, STMR, STMR - P)} & \\ \text{Exposure from } \textit{All other foods except animal food commodities} &= \\ \text{Total food consumption} \left( \frac{51 \frac{\text{g}}{\text{kg}} \text{ bw}}{\text{day}} \right) - \text{Food consumption for existing commodities with MRLs} & \\ \quad \times \text{Proposed } \textit{All other foods except animal food commodities} \text{ MRL concentration} & \end{aligned}$$

Figure 2: Estimating total dietary exposure from commodities with existing MRL permissions and *All other foods except animal food commodities* MRL

## 4.6 Acute Dietary Exposure Assessment

Acute (NESTI) dietary exposure assessments are undertaken where the OCS or JMPR has established an ARfD for an agvet chemical. Acute dietary exposures are normally only estimated for raw unprocessed commodities (fruit and vegetables) but may include meat, offal, cereal, milk or dairy products on a case-by-case basis.

For acute assessments, the highest residue from a supervised trial (HR) or MRL of an agvet chemical residue in a specific food commodity was multiplied by the 97.5<sup>th</sup> percentile commodity consumption amount (derived for consumers of that food only) to represent a 'high' consumer (large portion size). The commodity consumption for each individual was divided by their body weight to provide population estimates of the amount of the commodity consumed on a single day per kilogram (kg) of human body weight. A NESTI calculation was undertaken for the 2-6 year old population subgroup as well as for all Australians aged 2 years and above. Children aged 2-6 years were considered separately as the potential risk tends to be higher for young children relative to adults. This is because food consumption per kg of body weight is higher for these younger age groups as their energy requirements (met by eating food) need to cover developmental growth as well as maintenance needs.

Acute exposure = 'highest residue' chemical concentration x P97.5 commodity consumption

Four equations, set internationally, are used for calculating the NESTIs for different types of commodities. These equations are referred to as Case 1 (small unit weight), Case 2a (unit weight < large portion), Case 2b (unit weight > larger portion) and Case 3 (blended commodity) and represent various commodity 'unit weights' and portion sizes. The calculations and explanations are provided in Appendix A3.

The following commodities were used to estimate the worse-case acute dietary exposure for the 2-6 year old sub population as they were consumed in the highest amounts within each of the four types of food considered in Cases 1, 2a, 2b and 3 (worse case estimate):

- Case 1 Currants, red, black, white
- Case 2a Oranges, Sweet, Sour (Bigarade, Chinotto, Chironja)
- Case 2b - Pineapple
- Case 3 Milk

The following commodities were used to estimate the worst case acute dietary exposure for the population aged 2 years and above:

- Case 1 Grapes
- Case 2a Oranges, Sweet, Sour (Bigarade, Chinotto, Chironja)
- Case 2b Watermelon
- Case 3 Grapes, for juice

Grapes for Juice were used for Case 3 because they provide the worst case scenario for any commodity for which permissions may exist. Although water has the highest consumption amount (3.4 kg per person) for the Australian population aged 2 years and above, it is not a commodity to which agvet chemicals are applied.

For the purposes of the pilot in the Stage 1 screening, the NESTI for each agvet chemical was calculated using the screening MRL (chemical concentration of two times the LOR). In Stage 2, the NESTI calculations used the proposed *All other foods except animal food commodities* MRL as the highest residue likely to occur, to represent a worse-case scenario. Factors such as the highest residue on a composite sample of an edible portion, the supervised trials median residue or processing factors were not used in these calculations.

#### **4.6.1 Risk Characterisation**

For each agvet chemical in Stage 2, the estimated mean chronic dietary exposure (NEDI) was compared to the relevant ADI and where appropriate, the estimated acute dietary exposure (NESTI) was compared to the relevant ARfD to characterise risk to the Australian population. FSANZ considered that the chronic and acute dietary exposure to the residues of an agvet chemical were acceptable where the best estimates of mean chronic and acute dietary exposure did not exceed the ADI or ARfD respectively.

#### **4.6.2 Limitations and assumptions in the dietary exposure assessment**

FSANZ aims to make as realistic an estimate of dietary exposure as possible. However, where significant uncertainties in the data exist, conservative (or 'worst-case') assumptions may be used to ensure that the DEA does not underestimate exposure. In particular, for the 1995 NNS, there are limitations relating to the age of the data and the changes in eating patterns that may have occurred since these data were collected.

Assumptions used in this assessment for the purposes of the pilot include:

- food consumption data from the 1995 NNS represent current food consumption patterns
- where there are established MRLs for a commodity, the agvet chemical residue occurs in all of those commodities at the specified MRL, where median data (chronic DEA) or high residue data (acute DEA) were not available, including where the commodities were used in mixed foods
- where there is a proposed *All other foods except animal food commodities* MRL for an agvet chemical, the chemical residue was in all relevant food commodities for which there is no established MRL at the *All other foods except animal food commodities* MRL concentration, including where the commodities were used in mixed foods.

Overall, these assumptions will lead to a conservative (i.e. protective) estimate of dietary exposure. For more information on FSANZ dietary exposure assessment principles, methodology, assumptions and limitations and uncertainties of the concentration and food consumption data, see the FSANZ document, [Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes](#) (FSANZ, 2009a)<sup>8</sup>.

## 5 Review of principles and process for dietary exposure assessments (DEAs) including *All other foods except animal food commodities* MRLs

### 5.1 Summary

The pilot risk assessment approach resulted in FSANZ proposing 21 *All other foods except animal food commodities* MRLs. The outcome is summarised in Table 2.

**Table 2: Outcomes of the pilot**

Stages	Number in list	Comment
<b>Stage 1</b>		
Selected agvet chemicals for assessment in the pilot	132	NRS, APVMA suggestions, submissions
Exclusion criteria applied	92	Schedule 7 poison (the SUSMP), ERL, not in Code, etc.
NESTI >100% ARfD	89	For individual foods with existing MRLs
NEDI >100% ADI, including <i>All other foods except animal food commodities</i>	74	2xLimit of Determination/Q used as screening MRL for <i>All other foods except animal food commodities</i>
80/20 principle applied to estimated total exposure	19	Assessed on case-by-case basis in <b>Stage 2</b>
<b>Stage 2</b>		
<i>All other foods except animal food commodities</i> MRL proposed	19	Additional MRLs proposed for parent or related agvet chemical residues where relevant

<sup>8</sup> <http://www.foodstandards.gov.au/science/exposure/Pages/dietaryexposureand4438.aspx>

## 5.2 Conclusions

- The exercise undertaken for Proposal P1027 demonstrated that it is feasible to develop principles and a process for proposing *All other foods except animal food commodities* MRLs for agvet chemicals.
- The process for setting *All other foods* MRLs is not suitable for capturing inadvertent presence of pesticide residues in animal food commodities. Animal food commodities are therefore excluded from an *all other foods* MRL and the new description is *All other foods except animal food commodities* MRLs.
- The graduated risk analysis approach taken in the pilot resulted in a manageable number of agvet chemicals to work with and succeeded in proposing 19 *All other foods except animal food commodities* MRLs based on sound risk assessment.
- The DEA approach used a set of criteria and assumptions that resulted in 'worst case scenario' dietary exposure estimates when an *All other foods except animal food commodities* MRL was included in the estimate.
- The assumptions currently used in this proposal for the dietary exposure assessment for specific commodities are appropriate for establishing MRLs where the agvet pesticide is intentionally applied to protect specific crops.
- The principles of graduated risk assessment require criteria that result in a more refined estimate of potential dietary exposure to inadvertent agvet chemical residues. However, the outcome of the internal review of the pilot was that some of the assumptions (which are appropriately applied in routine exposure estimates in order not to underestimate dietary exposure) should be reconsidered when estimating exposure to inadvertent pesticide residues.
- FSANZ and the APVMA therefore considered that the assumption of 100% probability of the occurrence of agvet residue across the broad *All other foods except animal food commodities* category should be refined and a more realistic probability of occurrence (below 100%) be considered when estimating exposure to inadvertent pesticide residues.
- The full screening approach used in Stage 1 of Proposal P1027 would not be used for future risk assessments. However, FSANZ is proposing to include most of the Stage 1 exclusion criteria as the first step in the risk assessment process (see section 6 below) which can be applied to all agvet chemicals listed in the Code.

## 6 Future DEA process for setting *All other foods except animal food commodities* MRLs

The P1027 approach for DEAs for each agvet chemical in the future is as follows:

### 6.1 Step 1: Apply exclusion criteria

Agvet chemicals will be excluded from the setting of *All other foods except animal food commodities* MRLs as follows:

- Agvet chemical is not currently listed in Schedule 20
- Active constituent (agvet chemical) is not registered for use in Australia

- Active constituent of residue listed only as a Schedule 7 poison (the SUSMP)
- Agvet chemical is a veterinary medicine
- Agvet chemical has an ERL listed in Schedule 21
- Agvet chemical is currently nominated by the APVMA for formal review

➤ An *All other foods except animal food commodities* MRL will not be proposed for chemicals that meet one or more of the exclusion criteria

## 6.2 Step 2: DEA based on existing permissions

The following calculations were carried out for the agvet chemicals that were not excluded in Step 1.

- Estimate the acute dietary exposure to the residue from individual foods with existing MRLs where an ARfD has been established, using HR data, where available (NESTI)
- Estimate acute dietary exposure to the residue if present at or above the LOD
- If the NESTI < ARfD for all foods with an MRL, then estimate the chronic dietary exposure to the residue from all foods with existing MRLs using STMR or STMR-P data for concentration levels where available (NEDI).
- If the NEDI < ADI proceed to Step 3.

All MRL DEAs were based on 1995 NNS consumption data because food consumption data from the most recent National Nutrition and Physical Activity survey (NNPAS) component of the 2011–13 Australian Health Survey were not available.

➤ An *All other foods except animal food commodities* MRL will not be proposed for chemicals when existing permissions result in chronic and/or acute dietary exposures estimates equal to or greater than 100% of the relevant HBGV.

## 6.3 Step 3: DEA to propose *All other foods except animal food commodities* MRLs

For agvet chemicals that have not been excluded in Steps 1 or 2, the acute and chronic DEA calculations will be carried out using existing pesticide residue concentration data (MRL, STMR, STMR-P) for commodities with existing MRLs in Schedule 20 as above but this time including the proposed *All other foods except animal food commodities* MRL in the calculations.

The proposed *All other foods except animal food commodities* MRL will take into account:

- The numerical value of existing MRLs to determine the *highest* concentration at which an *All other foods except animal food commodities* MRL can be proposed, giving regard to GAP.
- The LOD relevant to the agvet chemical residue of interest to determine the lowest concentration at which an *All other foods except animal food commodities* MRL can be proposed, that is high enough to be practical for regulatory purposes.

### 6.3.1 Step 3a: Determine the estimated acute dietary exposure from *All other foods except animal food commodities* where an acute ARfD has been established

- Use the proposed *All other foods except animal food commodities* MRLs and the commodity identified for each NESTI case as the highest consumption amount for 2–6 year olds and the population aged 2 years and above.

- For agvet chemicals that result in acute dietary exposures estimates (NESTI) less than 100% of the relevant ARfD using the proposed MRL for *All other foods except animal food commodities*, a chronic DEA will be carried out.
- For agvet chemicals that result in acute dietary exposures estimates (NESTI) more than or equal to 100% of the relevant ARfD, the NESTI will be repeated using the lowest practical *All other foods except animal food commodities* MRL. If the NESTI <100% ARfD then a chronic DEA will be carried out.

### 6.3.2 Step 3b: Estimate total chronic dietary exposure including the contribution from *All other foods except animal food commodities*

- Estimate the total chronic dietary exposure to the agvet chemical from foods with existing MRLs using STMR or STMR-P data (where available) and from *All other foods except animal food commodities* using the proposed *all other foods except animal food commodities* MRL, assuming 10% of *All other foods except animal food commodities* contain the agvet chemical residue due to inadvertent use (NEDI).
- Calculate the percentage contribution of *All other foods except animal food commodities* to total chronic dietary exposure.

- If the total chronic dietary exposure (NEDI) at the lowest proposed *All other foods except animal food commodities* MRL that has been considered exceeds 100% of the HBGV, no *All other foods except animal food commodities* MRL can be proposed for inclusion in the Code.
- If the total chronic dietary exposure (NEDI) at the proposed *All other foods except animal food commodities* MRL is lower than 100% of the HBGV, the proposed *All other foods except animal food commodities* MRL may be adjusted on a case by case basis until the percentage contribution of *All other foods except animal food commodities* to total chronic dietary exposure is less than or equal to 20% of total dietary exposure (providing the NESTI using the proposed *All other foods except animal food commodities* MRL remains <100% ARfD).
- If the proposed *All other foods except animal food commodities* MRL will not contribute in excess of 20% of the total chronic dietary exposure or result in an acute dietary exposure estimate that exceeds the ARfD, then the *All other foods except animal food commodities* MRL for the chemical residue can be included in a FSANZ or APVMA proposal to change the Code.

## 7 References

FSANZ (2009). *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes*.  
[http://www.foodstandards.gov.au/science/exposure/Documents/Principles%20\\_%20practices%20exposure%20assessment%202009.pdf](http://www.foodstandards.gov.au/science/exposure/Documents/Principles%20_%20practices%20exposure%20assessment%202009.pdf)

WHO/FAO (2009a) Environmental Health Criteria 240 Principles and Methods for the Risk Assessment of Chemicals in Food. A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization.  
[http://www.inchem.org/documents/ehc/ehc/ehc240\\_index.htm](http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm)

WHO (2009b) *Acute and chronic hazard exposure assessments*. Joint FAO/WHO Meeting on Pesticide Residues. [http://www.who.int/foodsafety/chem/acute\\_data/en/](http://www.who.int/foodsafety/chem/acute_data/en/)



## Appendix A1 – Stage 1 - Chemicals for assessment

The application of screening criteria to the initial list of 132 agvet chemicals resulted in 19 agvet chemicals short-listed for consideration in P1027 (Table 3). A list of the agvet chemicals that were excluded and the reason for their exclusion is provided at Appendix A4. It should be noted that the establishment of an *All other foods except animal food commodities* MRL is dependent on the outcome of the DEA at Stage 2, (see below).

**Table 3: Agvet Chemicals progressed to Stage 2 following Stage 1 screening**

Agvet Chemical	Estimated dietary exposure, expressed as a %ADI based on current permissions
2-Phenylphenol	14% (7% citrus only)
Ametoctradin	<1%
Azoxystrobin	33%
Bifenthrin	44%
Captan	31%
Cyfluthrin	45%
Deltamethrin	69%
Fenhexamid	9%
Fludioxonil	29%
Glyphosate	9%
Iprodione	64%
Methomyl and Thiodicarb	39%
Penthiopyrad	7%
Pyrimethanil	24%
Spinosad	42%
Thiabendazole	48%
Triadimefon <sup>1</sup> and Triadimenol	26%

<sup>1</sup> Dietary exposure expressed as sum of triadimefon and triadimenol

## Appendix A2 – Stage 2 - Dietary exposure assessments including *All other foods except animal food commodities*

Details of the individual assessment of each agvet chemical are provided below. Any references to an agvet chemical, MRL or the range of MRLs or commodities below, refers to current permissions in Schedule 20 of the Code.

While the Limit of Determination is the lowest MRL at which an *All other foods except animal food commodities* MRL can be set, it may not be desirable to do so as it may not be high enough to allow for inadvertent presence of the chemical in the food. Therefore, an *All other foods except animal food commodities* MRL that is higher than the Limit of Determination has been proposed for each chemical based on the range of MRLs, the number of commodities with current MRLs and the contribution of *All other foods except animal food commodities* to the estimated total dietary exposure.

A summary of the outcomes of assessment of the agvet chemicals considered in Stage 2 is provided in Appendix A3, including details of relevant HBGVs for each agvet chemical.

### 2-Phenylphenol

Considerations	Comments
Limit of Determination	0.05 mg/kg
Lowest plant commodity MRL	10 mg/kg
Magnitude of existing plant commodity MRLs	The range of values for existing MRLs (was 3 mg/kg (cherries) to 25 mg/kg (pears). However, the registered uses have since changed and the Schedule is in the process of being amended by the APVMA. The result will be a single registered use and consequent permission of 10 mg/kg for citrus fruit only.
Lowest plant commodity MRL that is not the Limit of Determination	10 mg/kg
Most relevant reference point to minimise off-label use	0.1 mg /kg (2 x the Limit of Determination)
Chronic dietary exposure (NEDI) considering existing permissions only	14% of the ADI with existing permissions and 6% when the proposed registered use for citrus fruits only is included
Proposed <i>All other foods except animal food commodities</i> MRL	0.1 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	15% of the ADI with existing permissions and 7% when the proposed registered use for citrus fruits only is included
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg would result in a contribution of 5%/12% of the estimated total dietary exposure (existing permissions / citrus fruits only permission respectively).
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is not required for 2-Phenylphenol. This compound was considered by the OCS to have low acute toxicity, therefore no acute reference dose has been established.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg</b> for 2-Phenylphenol is considered acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Ametoctradin

Considerations	Comments
Limit of Determination	0.02 mg/kg
Lowest plant commodity MRL	0.05 mg/kg (potato)
Magnitude of existing plant commodity MRLs	The range of existing MRLs is 0.05 mg/kg (potato) to 50 mg/kg (leafy vegetables).
Lowest plant commodity MRL that is not the Limit of Determination	0.05 mg/kg (potato)
Most relevant reference point to minimise off-label use	0.4 mg/kg (cucumber). Although potato has a lower MRL, the agvet chemical is applied to the leaves above ground and therefore the MRL for the edible portion is not considered as an appropriate reference point.
Chronic dietary exposure (NEDI) considering existing permissions only	<1% of the ADI
Proposed <i>All other foods except animal food commodities</i> MRL	0.2 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	<1% of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg results in a contribution of 14% to the estimated total dietary exposure. Increasing the <i>All other foods except animal food commodities</i> MRL to 0.15 mg/kg is still within the target of 20% contribution to total dietary exposure. However, this was rounded up to 0.2 mg/kg which increased the contribution to 25% of total estimated exposure. Although slightly above the 20% target, considering the total estimated dietary exposure for Ametoctradin is currently less than 1% of the HBGV from foods with existing MRLs, this is considered acceptable.
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is considered unnecessary for Ametoctradin because the OCS has not established an acute reference dose and JMPR consider an ARfD unnecessary.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.2 mg/kg</b> for Ametoctradin is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Azoxystrobin

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	*0.01 mg/kg (almonds, cotton seed and maize) (*denotes set at the Level of Determination)
Magnitude of existing plant commodity MRLs	The range of existing MRLs is 0.01 mg/kg (almonds, cotton seed and maize) to T50 mg/kg (there are currently 15 commodities at this level). The highest non temporary MRL is 15 mg/kg (lettuce head, lettuce leaf).
Lowest plant commodity MRL that is not the Limit of Determination	0.05 mg/kg (peanut and potato)
Most relevant reference point to minimise off-label use	0.1 mg/kg (fennel, bulb; galangal, greater; oats; peanut oil, crude; turmeric, root and wheat).
Chronic dietary exposure (NEDI) considering existing permissions only	33% of the ADI
Proposed <i>All other foods except animal food commodities</i> MRL	0.1 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	35 % of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.01 mg/kg could have been used as this represented a contribution of <1% of the estimated total dietary exposure. Increasing the <i>All other foods except animal food commodities</i> MRL to 0.1 mg/kg is still within the target and represents a contribution of 10% to total dietary exposure. Although well below the 20% target, increasing the MRL beyond 0.1 mg/kg is considered inappropriate as it may facilitate off-label use.
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is considered unnecessary for Azoxystrobin because the OCS has not established an acute reference dose and JMPR consider an ARfD unnecessary.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg</b> for Azoxystrobin is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about existing risk to public health.

## Bifenthrin

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	There are three current MRLs established at or around the limit of determination: <ul style="list-style-type: none"> <li>*0.01 mg/kg - field peas (dry); ginger, root; grapes; peas (pods and succulent, immature seeds); pineapple; sugarcane.</li> <li>*0.02 mg/kg - cereal grains; poppy seed; pulses [except field pea (dry), lupin (dry)]; rape seed (canola)</li> <li>*0.05 mg/kg - apple; citrus fruits; sweet potato</li> </ul>
Magnitude of existing plant commodity MRLs	The range of existing MRLs is 0.01 mg/kg (see above) to T10 mg/kg (10 commodities at this MRL). The highest permanent MRL is 5 mg/kg for tea, green, black.
Lowest plant commodity MRL that is not the Limit of Determination	0.1 mg/kg (avocado; banana; cotton seed; fruiting vegetables, cucurbits [except cucumber])
Most relevant reference point to minimise off-label use	0.05 mg/kg (apple; citrus fruits; sweet potato). This is the highest of three MRLs set at the Limit of Determination.
Chronic dietary exposure (NEDI) considering existing permissions only	43% of the ADI
Proposed <i>All other foods except animal food commodities</i> MRL	0.03 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	51% of the ADI
Percentage contribution of All other foods except animal food commodities to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.01 mg/kg could have been used as this represents a contribution of 8% to total exposure. Setting the <i>All other foods except animal food commodities</i> MRL to 0.03 mg/kg is still within the target. Although 0.05 mg/kg is at the Limit of Determination for some commodities, setting the <i>All other foods except animal food commodities</i> MRL at this level results in estimated dietary exposure slightly above the 20% total dietary exposure target. Additionally, increasing the MRL beyond 0.03 mg/kg is considered inappropriate as it may facilitate off-label use.
Acute dietary exposure assessment (NESTI)	Children 2-6 years of age (worse case - pineapples), 10% of the ARfD Population aged 2 years and above (worse case - watermelon), 6% of the ARfD
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.03 mg/kg</b> for Bifenthrin is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Captan

Considerations	Comments
Limit of Determination	0.01 mg/kg for grain products and 0.05 mg/kg for horticulture products
Lowest plant commodity MRL	0.1 mg/kg (chick pea, dry)
Magnitude of existing plant commodity MRLs	The range of existing MRLs, excluding animal food commodities, is 0.1 mg/kg (chick pea, dry; lentil (dry)) to 30 mg/kg (berries and other small fruits [except grapes, strawberries and blueberries]).
Lowest plant commodity MRL that is not the Limit of Determination	0.1 mg/kg (chick pea, dry)
Most relevant reference point to minimise off-label use	0.1 mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	31% of the ADI
Proposed <i>All other foods except animal food commodities</i> MRL	0.1 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	34% of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.2 mg/kg could have been used as this represents 22% contribution to total dietary exposure. However, this level may encourage off-label use and therefore an MRL of 0.1 mg/kg is proposed. An <i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg represents a contribution of 13% to total dietary exposure and is considered acceptable.
Acute dietary exposure assessment (NESTI)	Children 2-6 years of age (worse case - pineapples), 10% of the ARfD.
	Population aged 2 years and above (worse case – watermelon), 6% of the ARfD.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg</b> for Captan is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Cyfluthrin

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	0.01 mg/kg (cotton seed)
Magnitude of existing plant commodity MRLs	The range of existing MRLs is 0.01 mg/kg (cotton seed) to 5 mg/kg (wheat bran, unprocessed).
Lowest plant commodity MRL that is not the Limit of Determination	0.01 mg/kg (cotton seed)
Most relevant reference point to minimise off-label use	0.05 mg/kg (rape seed, pecans, macadamia nuts)
Chronic dietary exposure (NEDI) considering existing permissions only	22% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.05 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	26% of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg represents a contribution of 18% to total dietary exposure and is within the target of 20% of total exposure.
Acute dietary exposure assessment (NESTI)	Children 2-6 years of age (worse case - pineapples), 13% of the ARfD.
	Population aged 2 years and above (worse case – watermelon), 8% of the ARfD.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg</b> for Cyfluthrin is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Deltamethrin

Considerations	Comments
Limit of Determination	0.01 mg/kg (0.005 mg/kg in the fat)
Lowest plant commodity MRL	*0.05 mg/kg (brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassica) (*indicates MRL set at or about the LOQ)
Magnitude of existing plant commodity MRLs	The range of existing MRLs is *0.05 mg/kg (brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassica) to 5 mg/kg (tea, green, black; wheat bran, unprocessed; and wheat germ). Where * indicates MRL set at or about LOQ.
Lowest plant commodity MRL that is not the Limit of Determination	0.1 mg/kg (fruiting vegetables, other than cucurbits; legume vegetables; oilseed; pulses; and sweet corn (kernels))
Most relevant reference point to minimise off-label use	0.1 mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	69% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.05 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	86% of the ADI.
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL set at 0.05 mg/kg contributes 19% to total dietary exposure.
Acute dietary exposure assessment (NESTI)	Children 2-6 years of age (worse case - pineapples), <1% of the ARfD.
	Population aged 2 years and above (worse case – watermelon), <1% of the ARfD.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg</b> for Deltamethrin is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health



## Fenhexamid

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	1.5 mg/kg (plums (including prunes))
Magnitude of existing plant commodity MRLs	The range of existing MRLs is 1.5 mg/kg (plums (including prunes)) to 50 mg/kg (lettuce, head, lettuce, leaf).
Lowest plant commodity MRL that is not the Limit of Determination	1.5 mg/kg (plums (including prunes))
Most relevant reference point to minimise off-label use	1.5 mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	9% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.1 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	11% of the ADI.
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 1.5 mg/kg could have been used as this is the lowest currently existing MRL for plant commodities. However, this represents a contribution of 76% to total dietary exposure which is well above the 20% target. Establishing the <i>All other foods except animal food commodities</i> MRL at 0.1 mg/kg represents a contribution of 17% to total dietary exposure and is considered acceptable.
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is considered unnecessary for Fenhexamid because the OCS has not established an acute reference dose and JMPR consider an ARfD unnecessary.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg</b> for Fenhexamid is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Fludioxonil

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	*0.01 mg/kg (broccoli; peanut; rape seed (canola); and sorghum) where * indicates MRL set at or about the LOQ.
Magnitude of existing plant commodity MRLs	The range of existing MRLs, excluding animal food commodities, is *0.01 mg/kg (broccoli; peanut; rape seed (canola); and sorghum) to 15 mg/kg (kiwifruit), where * indicates MRL set at the Limit of Determination.
Lowest plant commodity MRL that is not the Limit of Determination	0.01 mg/kg (peanut; rape seed (canola); and sorghum)
Most relevant reference point to minimise off-label use	0.01 mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	30% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.02 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	32% of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.01 mg/kg could have been used as this is the lowest existing MRL and represents 3% contribution to total exposure. However, being at the Limit of Determination it is not considered high enough to allow for the inadvertent presence of the agvet chemical in a commodity. Increasing the <i>All other foods except animal food commodities</i> MRL to 0.06 mg/kg represents a contribution of 17% to total dietary exposure and is within the target. However, this level is considered unacceptable as it is considerably higher than the current lowest MRL and may encourage off-label use. An MRL of 0.02 mg/kg represents a contribution of 6% to total dietary exposure and is considered acceptable.
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is considered unnecessary for Fludioxonil because the OCS has not established an acute reference dose and JMPR consider an ARfD unnecessary.
Conclusion	After considering the principles set out above an MRL for <b><i>All other foods except animal food commodities</i></b> of <b>0.02 mg/kg</b> for Fludioxonil is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health

## Glyphosate

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	*0.01 mg/kg (stalk and stem vegetables) (*denotes set at the Limit of Determination)
Magnitude of existing plant commodity MRLs	The range of existing MRLs, excluding animal food commodities, is *0.01 mg/kg (stalk and stem vegetables) to T20 mg/kg (lemon myrtle; poppy seed; and sunflower seed).
Lowest plant commodity MRL that is not the Limit of Determination	0.2 mg/kg (banana; cranberry; litchi; stone fruit; and tree nuts)
Most relevant reference point to minimise off-label use	0.2mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	9% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.2 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	10% of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.01 mg/kg could have been used as this represents a contribution of <1% to total dietary exposure. However, being at the Limit of Determination it is not considered high enough to allow for the inadvertent presence of the agvet chemical in a commodity. Increasing this to 0.3 mg/kg contributes less than 20% to total exposure. However, this level is considered too high and may encourage off-label use. An MRL of 0.2 mg/kg is within the target and represents a contribution of 13% to total dietary exposure and is considered acceptable.
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is considered unnecessary for Glyphosate because the OCS has not established an acute reference dose and JMPR consider an ARfD unnecessary.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.2 mg/kg</b> for Glyphosate is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health

## Iprodione

Considerations	Comments
Limit of Determination	0.01 mg/kg in grain products and 0.05 mg/kg in general horticultural crops
Lowest plant commodity MRL	*0.01 mg/kg (macadamia nuts) (*denotes MRL set at or about the Limit of Determination)
Magnitude of existing plant commodity MRLs	The range of existing MRLs in Schedule 1 of Standard 1.4.2 of the FSC (v155), excluding animal food commodities, is *0.01 mg/kg (macadamia nuts) to 20 mg/kg (grapes).
Lowest plant commodity MRL that is not set at or about the Limit of Determination	0.05 mg/kg (peanut; peanut oil, crude; and soya bean (dry))
Most relevant reference point to minimise off-label use	0.1 mg/kg (lupin (dry); beetroot)
Chronic dietary exposure (NEDI) considering existing permissions only	64% of the ADI
Proposed <i>All other foods except animal food commodities</i> MRL	0.1 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	71% of the ADI.
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>all other foods except animal food commodities</i> MRL of 0.01 mg/kg could have been used as this represents a contribution of <1% to total dietary exposure. However, being at the Limit of Determination it is not considered high enough to allow for the inadvertent presence of the agvet chemical in a commodity. Increasing this to 0.2 mg/kg represents 20% contribution to total dietary exposure. However, this level is considered too high and may encourage off-label use. An MRL of 0.1 mg/kg is within the target and represents a contribution of 11% to total dietary exposure and is considered acceptable.
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is considered unnecessary for Iprodione because neither the OCS nor JMPR has established an acute reference dose.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg</b> for Iprodione is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health

## Methomyl and Thiodicarb

Considerations	Comments
Combined assessment	Thiodicarb degrades into Methomyl and must be considered in setting Methomyl MRLs. An aggregate DEA is required if a Methomyl MRL is established for any commodity. Every Thiodicarb commodity must have a matching Methomyl commodity MRL, but not every Methomyl commodity needs a Thiodicarb entry. The use of both agvet chemicals on the same commodity is unlikely; therefore the DEA for Methomyl may be an overestimate.
Limit of Determination	0.01 mg/kg (horticultural products)
Lowest plant commodity MRL	*0.05 mg/kg (dried grapes; peanut; poppy seed) (0.05 mg/kg plantago ovata seed) Thiodicarb: *0.1 (cotton seed; cotton seed oil, crude; maize; potato; pulses; and sweet corn (corn-on-the-cob)) (*Denotes MRL set at or about the Limit of Determination)
Magnitude of existing plant commodity MRLs	The range of existing Methomyl MRLs, excluding animal food commodities, is 0.05 mg/kg (plantago ovata seed) to T10 mg/kg (coriander (leaves, stem, roots); herbs). (T denotes temporary MRL). The range of existing Thiodicarb MRLs, excluding animal food commodities, is 0.1 mg/kg (cotton seed; cotton seed oil, crude; maize; potato; pulses; and sweet corn (corn-on-the-cob)) to 5 mg/kg (peppers, sweet (capsicum)).
Lowest plant commodity MRL that is not the Limit of Determination	Methomyl and Thiodicarb: 0.05 mg/kg (plantago ovata seed)
Most relevant reference point to minimise off-label use	Methomyl: 0.05 mg/kg (dried grapes; peanut; plantago ovata seed; and poppy seed) Thiodicarb: 0.1 mg/kg (cotton seed; cotton seed oil, crude; maize; potato; pulses; and sweet corn (corn-on-the-cob))
Chronic dietary exposure (NEDI) considering existing permissions only	Methomyl: 16% of the ADI. Thiodicarb: 21% of the ADI. The combined exposures resulted in an estimated total dietary exposure of 37% of the ADI for Methomyl.
Proposed <i>All other foods except animal food commodities</i> MRL	Methomyl MRL of 0.05 mg/kg for <i>All other foods except animal food commodities</i> Thiodicarb MRL of 0.1 mg/kg for <i>All other foods except animal food commodities</i>
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	Methomyl and Thiodicarb: 51% of the ADI (overestimate of dietary exposure as this includes both agvet chemicals in <i>All other foods except animal food commodities</i> at the respective MRLs (i.e. 0.05 and 0.1 mg/kg))
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg for Methomyl represents a contribution of 12% to total dietary exposure. An <i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg is used for estimating Methomyl assuming the use is all from Thiodicarb. This represents a contribution of 22% to total dietary exposure. Although slightly above the 20% target, considering the total dietary exposure for Methomyl is currently 37% of the ADI and the fact that it is considered unlikely that both agvet chemicals would be used on the same commodity, the proposed <i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg for Methomyl and the <i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg for Thiodicarb are considered acceptable.
Acute dietary exposure assessment (NESTI)	Methomyl and Thiodicarb: Children 2-6 years of age (worse case - pineapples), 25% of the ARfD
	Methomyl and Thiodicarb: Population aged 2 years and above (worse case – watermelon), 15% of the ARfD

Considerations	Comments
Conclusion	After considering the principles set out above, the proposed <b><i>All other foods except animal food commodities</i></b> MRL of <b>0.05 mg/kg</b> for Methomyl and the <b><i>All other foods except animal food commodities</i></b> MRL of <b>0.1 mg/kg</b> for Thiodicarb are acceptable because they have been shown to be practical, adequately manage the risk of off-label use and do not increase the level of concern about risk to public health.

## Penthiopyrad

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	0.1 mg/kg (potato; tree nuts)
Magnitude of existing plant commodity MRLs	The range of existing MRLs, excluding animal food commodities, is 0.1 mg/kg (potato; tree nuts) to 70 mg/kg (brassica leafy vegetables).
Lowest plant commodity MRL that is not the Limit of Determination	0.1 mg/kg (potato; tree nuts)
Most relevant reference point to minimize off-label use	0.1 mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	7% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.05 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	8% of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total exposure	An <i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg could have been used as the lowest existing MRL for Penthiopyrad; however, this represents a contribution of 36% to total exposure. Reducing the <i>All other foods except animal food commodities</i> MRL to 0.05 mg/kg is required for it to remain within the target of 20% of total exposure. An <i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg represents a contribution of 18% to total dietary exposure and is considered acceptable.
Acute dietary exposure assessment (NESTI)	Children 2-16 years of age, all commodities resulted in <1% of the ARfD
	Population aged to years and above, all commodities resulted in <1% of the ARfD
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg</b> for Penthiopyrad is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Pyrimethanil

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	*0.01 mg/kg (Potato)
Magnitude of existing plant commodity MRLs	The range of existing MRLs, excluding animal food commodities, is 0.01 mg/kg (potato) to 20 mg/kg (lettuce, head and lettuce, leaf).
Lowest plant commodity MRL that is not the Limit of Determination	0.1 mg/kg (onion, bulb; spices)
Most relevant reference point to minimise off-label use	0.1 mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	24% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.1 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	26% of the ADI.
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.4 mg/kg could have been used as this represents a contribution of 19% to total dietary exposure. However, this level is considered unacceptable as it is considerably higher than the lowest existing MRLs for Pyrimethanil and may encourage off-label use. Establishing the <i>All other foods except animal food commodities</i> MRL at 0.1 mg/kg, represents a contribution of 6% to total dietary exposure and is well within the target and considered acceptable.
Acute dietary exposure assessment (NESTI)	Children 2-6 years of age (worse case - pineapples), 1% of the ARfD
	Population aged 2 years and above, all commodities resulted in <1% of the ARfD.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg</b> for Pyrimethanil is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.



## Spinosad

Considerations	Comments
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	0.01 mg/kg (pulses; coffee beans; cotton seed; safflower seed; tree nuts)
Magnitude of existing plant commodity MRLs	The range of existing MRLs is 0.01 mg/kg (pulses; coffee beans; cotton seed; safflower seed; tree nuts) to 5 mg/kg (bergamot; burnet, salad; chervil; chervil; coriander (leaves, stem, roots); dill, seed; fennel, seed; herbs; Japanese greens; kaffir lime leaves; leafy vegetables; lemon grass; lemon verbena (dry leaves); rucola (rocket)).
Lowest plant commodity MRL that is not the Limit of Determination	0.01 mg/kg (pulses)
Most relevant reference point to minimize off-label use	0.01 mg/kg)
Chronic dietary exposure (NEDI) considering existing permissions only	41% of the ADI.
Proposed <i>All other foods except animal food commodities</i> MRL	0.01 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	43% of the ADI
Percentage contribution of <i>All other foods except animal food commodities</i> to total exposure	An <i>All other foods except animal food commodities</i> MRL of 0.1 mg/kg could have been used as this represents a contribution of 23% to total dietary exposure. However, this level is considered unacceptable as it is considerably higher than the lowest existing MRLs for Spinosad and may encourage off-label use. Establishing the <i>All other foods except animal food commodities</i> MRL at 0.01 mg/kg, represents a contribution of 3% to total dietary exposure and is well within the target and considered acceptable.
Acute dietary exposure assessment (NESTI)	An acute dietary exposure assessment is considered unnecessary for Spinosad because the OCS has not established an acute reference dose and JMPR consider an ARfD unnecessary.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.01 mg/kg</b> for Spinosad is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Thiabendazole

Considerations	Comments
Limit of Determination	0.01 mg/kg However, at this level the <i>All other foods except animal food commodities</i> MRL is not high enough to allow for inadvertent presence of pesticide residues in a food commodity
Lowest plant commodity MRL	T*0.01 mg/kg (peanuts) (*Denotes MRL set at or about the Limit of Determination)
Magnitude of existing plant commodity MRLs	The range of existing MRLs is T*0.01 mg/kg (peanuts) to 10 mg/kg (apple; citrus fruits; pear).\
Lowest plant commodity MRL that is not the Limit of Determination	0.05 mg/kg (onion, bulb; sweet potato)
Most relevant reference point to minimise off-label use	0.05 mg/kg
Chronic dietary exposure (NEDI) considering existing permissions only	48% of the ADI (using the JMPR ADI value for women of childbearing age as a worst case).
Proposed <i>All other foods except animal food commodities</i> MRL	0.03 mg/kg
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	49% of the ADI (using the JMPR value for women of childbearing age as a worst case).
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.4 mg/kg could have been used as this represents a contribution of 21% to total dietary exposure. However, this level is considered unacceptable as it is considerably higher than the lowest existing MRLs for Thiabendazole and may encourage off-label use. Establishing the <i>All other foods except animal food commodities</i> (MRL at 0.03 mg/kg) represents a contribution of 2% to total dietary exposure and is well within the target and considered acceptable.
Acute dietary exposure assessment (NESTI)	The ARfD for the general population has been established at 1 mg/kg bw, while an ARfD of 0.3 mg/kg bw for Thiabendazole has been established for women of child bearing age. This lower ARfD has been used in the NESTI calculations, together with the estimated food consumption for Australians aged 2 years and above, to provide a conservative estimate of acute exposure.
Acute dietary exposure assessment (NESTI)	Children 2-6 years of age (worse case - pineapples), 2% of the ARfD Population aged 2 years and above (worse case – watermelon), 2% of the ARfD
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.03 mg/kg</b> for Thiabendazole is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Triadimefon and Triadimenol

Considerations	Comments
Combined assessment	Triadimefon is the parent compound of Triadimenol and therefore the establishment of an <i>All other foods except animal food commodities</i> for Triadimefon needs to also consider dietary exposure from the registered uses of Triadimenol. Where the same commodity has an MRL for both agvet chemicals, the commodity with the highest MRL is used in the exposure estimate. This assumes that Triadimefon breaks down to mostly Triadimenol and is likely to be an overestimate of dietary exposure.
Limit of Determination	0.01 mg/kg
Lowest plant commodity MRL	Triadimefon: *0.05 mg/kg (sugar cane) Triadimenol: *0.01 mg/kg (cereal grains [except sorghum]; cotton seed)
Magnitude of existing plant commodity MRLs	The range of existing Triadimefon MRLs is 0.05mg/kg (sugar cane) to 1 mg/kg (apples; grapes). The range of existing Triadimenol MRLs is *0.01mg/kg (cereal grains [except sorghum]) and T0.01 (cotton seed) to T3 mg/kg (chives; leek; onion, Chinese; onion, Welsh; shallot; spring onion). (* denotes MRL set at or about the Limit of Determination and T denotes temporary MRL).
Lowest plant commodity MRL that is not the Limit of Determination	Triadimefon: 0.1 mg/kg (field pea (dry); garden pea (shelled succulent seeds); garden pea (young pods, succulent seeds)) Triadimenol: 0.05 mg/kg (onion, bulb; cotton seed oil, crude)
Most relevant reference point to minimise off-label use	Triadimefon: 0.1 mg/kg Triadimenol: 0.05 mg/kg (cotton seed oil, crude)
Chronic dietary exposure (NEDI) (sum of exposure to Triadimefon and Triadimenol) considering existing permissions only	25% of the ADI (9% from Triadimefon).
Proposed <i>All other foods except animal food commodities</i> MRL	0.05 mg/kg establishing the <i>All other foods except animal food commodities</i> MRL at the same level for both agvet chemicals is considered appropriate.
NEDI including <i>All other foods except animal food commodities</i> MRL and existing permissions	Sum of Triadimefon and Triadimenol: 34% of the ADI.
Percentage contribution of <i>All other foods except animal food commodities</i> to total chronic exposure	An <i>All other foods except animal food commodities</i> MRL of 0.01 mg/kg could have been used as this represents a contribution of 4% to total dietary exposure (sum of exposure to Triadimefon and Triadimenol). Increasing the <i>All other foods except animal food commodities</i> MRL to 0.05 mg/kg is still within the target and represents a contribution of 18% to total dietary exposure. Considering the total dietary exposure for Triadimefon and Triadimenol is relatively low at 35% of the HBGV, this is considered acceptable.
Acute dietary exposure assessment (NESTI)	The JMPR established the same ARfD for both Triadimefon and Triadimenol. The acute exposure for Triadimefon is considered as the parent compound.
Acute dietary exposure assessment (NESTI)	Children 2-6 years of age (worse case - pineapples), 6% of the ARfD. Population aged 2 years and above (worse case – watermelon), 4% of the ARfD.
Conclusion	After considering the principles set out above an <b><i>All other foods except animal food commodities</i> MRL of 0.05 mg/kg for Triadimefon and Triadimenol</b> is acceptable because it has been shown to be practical, adequately manages the risk of off-label use and does not increase the level of concern about risk to public health.

## Appendix A3 – Summary of Dietary Exposure Assessments including *All other foods except animal food commodities* MRLs

Agvet Chemical	ADI (mg/kg bw) (Source)	ARfD (mg/kg bw) (Source)	NEDI (%ADI)	NESTI (%ARfD) 2-6 years	NESTI (%ARfD) 2+ years	Proposed <i>All other foods except animal food commodities</i> MRL (mg/kg)	Existing MRL range (mg/kg) (1.4.2 v158)
2 -Phenylphenol	0.4 (OCS)	Considered Unnecessary (OCS)	15% (including current FSC commodities) 7% (citrus fruit only)	Not required	Not required	0.1	10 All registered uses, except citrus fruits, are being withdrawn. Only citrus fruit will remain in APVMA Standard, however, currently other commodities in FSC (current range 3 – 5 mg/kg).
Ametoctradin	10 (OCS)	Not established (OCS)	<1%	Not required	Not required	0.2	Animal: *0.02 Plant: 0.05 - 50
Azoxystrobin	0.1 (OCS)	Not established (OCS)	35%	Not required	Not required	0.1	Animal: 0.005 – *0.01 Plant: *0.01 – T50
Bifenthrin	0.01 (JMPR)	0.01 (JMPR)	51%	Case 1 - 4% Case 2a – 7% Case 2b – 10% Case 3 – 8%	Case 1 - 2% Case 2a – 2% Case 2b – 6% Case 3 – 3%	0.03	Animal: *0.05 – 2 Plant: *0.01 - T10
Captan	0.1 (OCS)	0.1 (OCS)	34%	Case 1 - 4% Case 2a – 7% Case 2b – 10% Case 3 – 8%	Case 1 - 2% Case 2a – 2% Case 2b – 6% Case 3 – 3%	0.1	Animal: *0.01 - *0.05 Plant: T0.1 - T30

<b>Agvet Chemical</b>	<b>ADI (mg/kg bw) (Source)</b>	<b>ARfD (mg/kg bw) (Source)</b>	<b>NEDI (%ADI)</b>	<b>NESTI (%ARfD) 2-6 years</b>	<b>NESTI (%ARfD) 2+ years</b>	<b>Proposed All other foods except animal food commodities MRL (mg/kg)</b>	<b>Existing MRL range (mg/kg) (1.4.2 v158)</b>
Cyfluthrin	0.04 (JMPR)	0.04 (JMPR)	26%	Case 1 - 5% Case 2a - 8% Case 2b - 13% Case 3 - 10%	Case 1 - 2% Case 2a - 3% Case 2b - 8% Case 3 - 4%	0.05	Animal: *0.01 – 0.5 Plant: 0.01 – 5
Deltamethrin	0.05 (JMPR)	1.5 (JMPR)	86%	Case 1 - 2% Case 2a - 4% Case 2b - 6% Case 3 - <1%	Case 1 - 1% Case 2a - 1% Case 2b - 4% Case 3 - <1%	0.05	Animal: *0.01 – 0.5 Plant: *0.05 - 5
Fenhexamid	0.2 (OCS)	Not established (OCS)	11%	Not required	Not required	0.1	Animal: *0.01 – 2 Plant: T2 – T50
Fludioxonil	0.03 (OCS)	Not established (OCS)	32%	Not required	Not required	0.02	Animal: 0.05 – 0.1 Plant: *0.01 - 15
Glyphosate	0.3 (OCS)	Not established (OCS)	10%	Not required	Not required	0.2	Animal: *0.05 – 2 Plant: *0.01 - T20
Iprodione	0.04 (OCS)	Not established (OCS)	71%	Not required	Not required	0.1	Animal: *0.1 Plant: *0.01 - 20
Methomyl and Thiodicarb	0.02 (JMPR)	0.02 (JMPR)	51%	Case 1 - 10% Case 2a - 17% Case 2b - 25% Case 3 – 20%	Case 1 - 4% Case 2a - 5% Case 2b - 15% Case 3 - 8%	0.05 (Methomyl) 0.1 (Thiodicarb)	Animal: *0.02 – 0.05 Plant: *0.05 - T10
Penthiopyrad	0.1 (OCS)	0.75 (OCS)	8%	Case 1 - <1% Case 2a - <1% Case 2b - <1% Case 3 - 1%	All cases <1%	0.05	Animal: *0.02 – 0.05 Plant: 0.1 - 70
Pyrimethanil	0.2 (OCS)	0.85 (OCS)	26%	Case 1 - <1% Case 2a - <1% Case 2b - 1% Case 3 - 1%	Case 1 - <1% Case 2a - <1% Case 2b - 1% Case 3 - 1%	0.1	Animal: *0.01 - *0.05 Plant: *0.01 - 20
Spinosad	0.02 (OCS)	Not established	43%	Not required	Not required	0.01	Animal: 0.05 – 2 Plant: *0.01 - 5

<b>Agvet Chemical</b>	<b>ADI (mg/kg bw) (Source)</b>	<b>ARfD (mg/kg bw) (Source)</b>	<b>NEDI (%ADI)</b>	<b>NESTI (%ARfD) 2-6 years</b>	<b>NESTI (%ARfD) 2+ years</b>	<b>Proposed All other foods except animal food commodities MRL (mg/kg)</b>	<b>Existing MRL range (mg/kg) (1.4.2 v158)</b>
Thiabendazole	0.1 (JMPR)	0.3 (JMPR – established for women of child bearing age) (1 mg/kg for general population)	49%	Case 1 - 1% Case 2a - 1% Case 2b - 2% Case 3 - 1%	Case 1 - 1% Case 2a - 1% Case 2b - 2% Case 3 - 1%	0.03	Animal: 0.05 – 0.2 Plant: T*0.01 - 10
Triadimefon and Triadimenol	0.03 (JMPR)	0.08 (JMPR)	34% (sum of exposures)	Case 1 - <3% Case 2a - <4% Case 2b - <6% Case 3 - 5%	Case 1 - <1% Case 2a - <1% Case 2b - <4% Case 3 - 2%	0.05	(Triadimefon) Animal: *0.05 – *0.25 Plant: *0.05 - 1 (Triadimenol) Animal: *0.01 Plant: *0.01 - T3

## Appendix A4 – List of agvet chemicals excluded from further consideration at Step 1

Agvet Chemical	Reason for exclusion
2,4-Dichlorophenoxyacetic Acid (2,4-D)	estimated dietary exposure >80% ADI
Abamectin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Acephate	estimated dietary exposure >80% ADI, APVMA review chemical
Acetamiprid	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Aldrin And Dieldrin	ERL
Azinphos-Methyl	Schedule 7 poison
Benalaxyl	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Bioresmethrin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Bitertanol	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Buprofezin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Carbaryl	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Carbendazim	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Chlorfenapyr	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Chlorfenvinphos	Schedule 7 poison
Chlorothalonil	APVMA review chemical
Chlorpyrifos	estimated dietary exposure >80% ADI
Chlorpyrifos-Methyl	estimated dietary exposure >80% ADI
Chlorthal-Dimethyl	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Clofentezine	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Cloquintocet-Mexyl	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Coccidiostat Residues.	unsure if these are included/excluded
Cyhalothrin	Schedule 7 poison

<b>Agvet Chemical</b>	<b>Reason for exclusion</b>
Cyproconazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Cyprodinil	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
DDT	ERL
Diazinon	estimated dietary exposure >80% ADI
Dichlorvos	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Dicloran	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Dicofol	APVMA review chemical
Difenoconazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Dimethoate	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Dimethomorph	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Diphenylamine	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Disulfoton	estimated dietary exposure >80% ADI
Diuron	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Endosulfan	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Endrin	estimated dietary exposure >80% ADI Schedule 7 Poison
Ethion	Schedule 7 poison
Ethoprophos	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Fenamiphos	estimated dietary exposure >80% ADI
Fenarimol	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Fenitrothion	Estimated dietary exposure >80% ADI
Fenoxycarb	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Fenpyroximate	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Fenthion	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Fenvalerate	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%



<b>Agvet Chemical</b>	<b>Reason for exclusion</b>
Fipronil	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Flusilazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Fluvalinate	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Haloxypop	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
HCB (Hexachlorobenzene)	ERL
Hch (Bhc)	ERL
Heptachlor	ERL
Hexaconazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Hexythiazox	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Imazalil	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Indoxacarb	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Isoprothiolane	not listed in Schedule 1 of 1.4.2
Kresoxim-methyl	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Lindane	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Linuron	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Malathion (listed In Code as Maldison)	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Metalaxyl	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Methamidophos	estimated dietary exposure >80% ADI
Methidathion	Schedule 7 poison
Mevinphos	estimated dietary exposure >80% ADI Schedule 7 Poison
Milbemectin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Monensin (LOQ=1)	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Monocrotophos	estimated dietary exposure >80% ADI Schedule 7 Poison
Myclobutanil	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%

<b>Agvet Chemical</b>	<b>Reason for exclusion</b>
Nicarbazin (LOQ=10)	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Ortho-Phenylphenol	see 2-phenylphenol
Oxadixyl	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Oxyfluorfen	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Paclobutrazol	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Parathion-Ethyl	estimated dietary exposure >80% ADI
Parathion-Methyl	estimated dietary exposure >80% ADI
Penconazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Pendimethalin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Permethrin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Phenothrin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Phorate	Schedule 7 poison
Phosmet	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Piperonyl-Butoxide	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Pirimicarb	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Pirimiphos-Methyl	estimated dietary exposure >80% ADI
Prochloraz	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Procymidone	Schedule 7 poison
Profenofos	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Propargite	estimated dietary exposure >80% ADI
Propiconazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Prothioconazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Prothiofos	estimated dietary exposure >80% ADI
Pymetrozine	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%

<b>Agvet Chemical</b>	<b>Reason for exclusion</b>
Pyraclostrobin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Pyrethrins	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Pyriproxyfen	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Quintozene	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Semicarbazide	not listed in Schedule 1 of 1.4.2
Spirotetramat	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Sulfuryl Fluoride	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Tebuconazole	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Tebufenozide	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Tebufenpyrad	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Terbufos	Schedule 7 poison
Tetradifon	estimated dietary exposure >80% ADI
Thiacloprid	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Thiamethoxam	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Trichlorfon	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Tricyclazole	not listed in Schedule 1 of 1.4.2
Trifloxystrobin	the percentage contribution of <i>All other foods except animal food commodities</i> to estimated total dietary exposure in a preliminary screen exceeded 20%
Vinclozolin	Schedule 7 poison

## **Appendix A5 – National Nutrition Surveys used in the dietary exposure assessments**

### **2007 Australian National Children's Nutrition and Physical Activity Survey**

The 2007 ANCNPAS collected data on nutrition and physical activity for 4,487 children aged 2–16 years across Australia. The survey was conducted over a seven month time period, from February to August 2007.

In contrast to other national nutrition surveys used to date by FSANZ (the 1995 Australian and 2008 and 2002 New Zealand surveys), for the 2007 ANCNPAS each respondent completed two 24-hour recalls on non-consecutive days. The availability of two days of food consumption data provides a more realistic estimate of long term consumption of infrequently consumed foods, because it takes account of those who may eat a food on one day of the survey but not on the other. Using one 24-hour recall may capture an unusual eating occasion for an individual that does not describe how they normally eat. These data are used weighted.

### **1995 NNS**

The 1995 NNS provides comprehensive information on dietary patterns of a sample of 13,858 Australians aged from 2 years and above. It is the most recent NNS for Australians aged 17 years and above currently available to FSANZ in its dietary exposure assessment analysis database. 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. These data are used unweighted.

## Appendix A6 – NESTI Calculations

This Appendix outlines the different cases used in National Estimates of Short Term Intake (NESTI) Calculations. Additional explanation of these equations is provided by the FAO/WHO (2009) [Environmental Health Criteria 240 Principles And Methods for the Risk Assessment of Chemicals in Food](#), a joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization<sup>9</sup>.

### Case 1

The concentration of residue in a composite sample (raw or processed) reflects that in a meal-sized portion of the commodity (unit weight is <25 g, for example peas or grapes). This case also applies to meat, liver, kidney, edible offal and eggs and for grains, oil seeds and pulses when the estimate of the HR or HR-P was based on post-harvest use of the pesticide.

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

### Case 2

The meal-sized portion, such as a single piece of fruit or vegetable, might have a higher residue than the composite (unit weight of the whole portion is >25 g). A default variability factor of 3 is applied in the equations. When sufficient data are available on residues in single units to calculate a more realistic variability factor for a commodity, the calculated value replaces the default value.

When data are available on residues in a single unit allowing estimation of the highest residue in a single unit, this value should be used in the first term in the numerator of the equation for case 2a, with variability factor.

The HR value derived from the data on composite samples should be used in the second term. For case 2b, the estimated highest residue in a single unit should be used in the equation with no variability factor.

### Case 2a

The unit weight of the whole commodity is lower than that of the large portion, LP (for example apples).

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

### Case 2b

The unit weight of the whole commodity is higher than that of the large portion, LP (for example watermelon).

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

### Case 3

When a processed commodity is bulked or blended, the STMR-P value represents the probable highest residue. This case also applies to milk and to grains, oil seed and pulses when the estimate of the STMR or STMR-P was based on pre-harvest use of the pesticide.

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

<sup>9</sup> [http://www.inchem.org/documents/ehc/ehc/ehc240\\_index.htm](http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm)