

14 May 2020 [121-20]

## **Supporting Document 1**

Dietary exposure assessments and MRL changes – Proposal M1017

Maximum Residue Limits (2019)

## **Executive summary**

This Supporting Document provides information relating to the results of the dietary exposure assessments (DEA) undertaken for the requested agricultural and veterinary (agvet) chemicals and food commodities for the 2019 Maximum Residue Limit (MRL) Harmonisation Proposal, M1017.

A DEA was undertaken for each of the requested chemicals which met the FSANZ MRL policy requirements and where the Australian Pesticides and Veterinary Medicines Authority (APVMA) or the Joint Food and Agriculture Organization / World Health Organization Meeting on Pesticide Residues (JMPR) have established a relevant Health Based Guidance Value (HBGV), such as an Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD). Where there was no APVMA or JMPR HBGV and the agvet chemical is or has been previously listed in schedule 20, another authoritative source of HBGV for the DEA was used. The DEA methods used are consistent with internationally accepted methodologies, the APVMA's risk assessment framework for approving and registering agricultural chemical products for use in Australia and the process used by both the APVMA and FSANZ for establishing and reviewing MRLs in schedule 20 of the Code.

The National Estimated Daily Intake (NEDI) was calculated for each of the requested chemicals and food commodities to represent chronic dietary exposure. The NEDI estimate was then compared to the Acceptable Daily Intake (ADI) for that chemical. The National Estimated Short Term Intake (NESTI) was also calculated for an acute (short-term) dietary exposure for each of the requested chemicals and food commodities and then compared to the relevant Acute Reference Dose (ARfD), if established.

The food consumption data used for the dietary exposure assessment were sourced from the 2011–12 National Nutrition and Physical Activity Survey (NNPAS), a component of the 2011–13 Australian Health Survey. The mean food consumption data for all survey respondents (n=7,735, aged 2 years and above) were used for the NEDI. This mean value represents the average consumption of a food commodity for the whole population. For the NESTI calculations, food consumption data at the 97.5<sup>th</sup> percentile for all respondents (aged 2 years and above) were extracted. To derive NESTI estimates for specific sub-population groups, 97.5<sup>th</sup> percentile food consumption data for the groups were also derived. The population sub-groups included children aged 2–6 years and women of childbearing age (16–44 years).

An additional assessment was conducted for the agvet chemicals to determine their suitability for the establishment of an *All other foods except animal food commodities* MRL. For agvet chemicals with an existing *All other foods except animal food commodities* MRL the limit was reviewed. The assessment process for this MRL category followed the principles set out in *Proposal P1027 – Managing Low-level Ag & Vet Chemicals without Maximum Residue Limits*. The proposed MRLs for the category allow for low level inadvertent presence of chemical residues in food following legitimate use, whilst aiming to limit 'off-label' use.

The dietary exposure estimates for all chemicals with proposed MRLs in M1017 do not exceed the relevant HBGVs, indicating negligible health and safety concerns to Australian consumers. The proposed MRL changes, origin of requests, commodity descriptions, comparisons with Codex MRLs and the dietary exposure estimates for the Australian population are given in Table 1 of this document. The summaries of existing or proposed *All other foods except animal food commodities* MRLs are set out in the Appendix.

# Table of contents

EX	<b>ECUTI</b>	IVE SUMMARY
		RODUCTION
		RONIC DIETARY EXPOSURE ASSESSMENT
		JTE DIETARY EXPOSURE ASSESSMENT
4.	ALL	OTHER FOODS EXCEPT ANIMAL FOOD COMMODITIES MRLS
5.	FOO	DD CONSUMPTION DATA USED
		NEDI CALCULATION
6.	RES	SULTS OF ASSESSMENT
		APPENDIX – DIETARY EXPOSURE ASSESSMENT SUMMARIES FOR THE PROPOSED ALL OTHER FOODS

## 1. Introduction

This Supporting Document provides information relating to the results of the dietary exposure assessments undertaken for each of the requested agvet chemicals and food commodities included in the 2019 MRL Harmonisation Proposal, M1017.

The harmonisation requests sought to align MRLs in schedule 20 of the *Australian New Zealand Food Standards Code* (the Code) with MRLs proposed by the requestors which were either established by the Codex Alimentarius Committee (Codex) or the countries in which the foods were produced. These standards all reflect legitimate international use of permitted agvet chemicals in the production of the food commodities. The proposal also included requests from the Australian Pesticides and Veterinary Medicines Authority (APVMA) to align the Code with the APVMA MRL Standard, including the removal or reduction of certain MRLs.

The risk assessment estimated dietary exposures for all agvet chemicals where the APVMA or JMPR had established a relevant Health Based Guidance Value (HBGV), such as an Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD). On occasions, when a HBGV was not established by the APVMA or JMPR, an alternate HBGV was used.

For each chemical considered in this proposal the existing *All other foods except animal food commodities* MRLs were reviewed and where appropriate, an additional assessment was conducted for suitability to establish *All other foods except animal food commodities* MRLs. Assessment and allocation of this MRL category followed the principles set out in *Proposal P1027 – Managing Low-level Ag & Vet Chemicals without Maximum Residue Limits*.

The methods used for the dietary exposure estimates are consistent with internationally accepted methodologies, with the APVMA's risk assessment framework for approving and registering agricultural chemical products in Australia and the process used by both the APVMA and FSANZ for establishing and reviewing MRLs in schedule 20.

# 2. Chronic Dietary Exposure Assessment

The National Estimated Daily Intake (NEDI) represents an estimate of chronic dietary exposure. In chronic dietary exposure assessments, the chemical residues in all the food commodities that could result from the permitted use of the agricultural chemicals are considered. Chemical residue trial data, as opposed to the MRL, are the preferred concentration data used if available, as they provide a more realistic estimate of dietary exposure. Processing factors for certain commodities are also taken into consideration.

The estimated mean dietary exposure from each food commodity is added together to provide the total mean dietary exposure to a chemical from all foods with MRLs. The estimated mean dietary exposure is divided by the mean body weight for the population to provide the amount of chemical consumed per day per kg of body weight for the Australian population. This result is then compared to the Acceptable Daily Intake (ADI) established for the chemical.

The NEDI calculation may incorporate more specific data as appropriate. The NEDI calculation may also take into account factors such as the proportion of the crop or commodity treated with the chemical, the residues in edible portions and the effects of

processing and cooking on the residue levels. It may use supervised trials median residue (STMR) levels rather than the MRLs to represent chemical residue levels. Chemical concentration data from monitoring and surveillance activities or the Australian Total Diet Studies (ATDS) may also be used if necessary.

If data are not available on the specific residues in a food, a cautious approach is taken and the MRL value is used in the calculation. However, use of the MRL in dietary exposure estimates may result in considerable overestimates of exposure because this approach assumes that:

- the agricultural chemical will be used on all crops for which there is a registered use or an approved permit
- treatment occurs at the maximum application rate
- the maximum number of permitted treatments have been applied
- the minimum withholding period applies
- the entire crop and food supply contains residues equivalent to the MRL.

In reality, only a portion of a specific crop is treated with the chemical and most treated crops at harvest contain residues well below the MRL. The levels of residues are usually reduced during storage, preparation, commercial processing, and cooking. It is also unlikely that every food for which an MRL is proposed will have been treated with the same pesticide throughout the lifetime of consumers that eat those foods. However, for the purposes of undertaking a risk assessment, it is prudent to be protective of consumers, particularly in the absence of data that could further refine the dietary exposure estimates.

The NEDI presented as a percent of the HBGV (ADI) in Table 1 includes all foods with existing MRLs, the foods requested in this proposal and all other foods except animal food commodities where an MRL has been proposed.

# 3. Acute Dietary Exposure Assessment

The National Estimated Short Term Intake (NESTI) is used to estimate acute (short-term) dietary exposure. Acute dietary exposure assessments are undertaken where the APVMA has set an ARfD for a chemical or advised it is appropriate to use a JMPR ARfD. The established ARfD is used for NEDI assessments for the population aged 2 years and above and children 2-6 years. An acute dietary exposure assessment is only undertaken for women of childbearing age (16-44 years) where a specific ARfD for this group is established.

The NESTI is calculated in a similar way to chronic dietary exposure, but uses the ARfD rather than ADI as the HBGV and food consumption data at the 97.5th percentile instead of the mean. The calculation can take into account factors such as the highest residue on a composite sample of an edible portion, the STMR, processing factors (which affect changes from the raw commodity to the consumed food) and a 'variability factor' (to account for variations in residues between individual pieces of a commodity) where appropriate.

The exact equations for calculating the NESTI differ depending on the type or size of the commodity. These equations are agreed and used internationally. The calculations provide information on the level of exposure to a chemical from consuming an individual food commodity (e.g. wheat) and take into account the consumption of processed foods that contain the commodity (e.g. apple pie and bread). The estimated exposure for each

individual food is compared to the ARfD. Unlike the NEDI, the calculations are done for each commodity individually; there is no summing of exposures across foods. A NESTI calculation may include food consumption data for particular sub-groups of the population.

# 4. All other foods except animal food commodities MRLs

All agvet chemicals that required a dietary exposure assessment were considered for suitability for setting an *All other foods except animal food commodities* MRL using the principles established in P1027. Both chronic and, where appropriate, acute dietary exposures were considered. The proposed MRLs are high enough to allow for inadvertent presence of the chemical in food from legitimate use but low enough to limit the potential for 'off-label' use of the chemical. This approach is consistent with the APVMA's risk assessment framework for approving and registering agvet chemical products, and with the risk assessment approach for establishing MRLs in the Code.

Agvet chemicals that are not considered for setting *All other foods except animal food commodities* MRLs are the following:

- Agvet chemical is not currently listed in schedule 20
- Active constituent (agvet chemical) is not registered for use in Australia
- Active constituent is listed only in Schedule 7 of the Poisons Standard of the Therapeutic Goods Administration
- Agvet chemical is primarily used as a veterinary medicine
- Agvet chemical has an Extraneous Residue Limit 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)
- Agvet chemicals where 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
- Acute dietary exposure estimate exceeded the acute reference dose (ARfD), using a 'worst case' commodity consumption amount and the proposed MRL for All other foods except animal food commodities.

# 5. Food consumption data used

#### 5.1 NEDI calculation

Mean food consumption data derived from all respondents (eaters and non-eaters of the foods containing the chemical residue) were used for NEDI calculations. The consumption amounts were derived from respondents (n=7,735) who had two days of 24-hour recall data from the 2011–12 National Nutrition and Physical Activity Survey (NNPAS), which was a component of the 2011–13 Australian Health Survey. The two days of data were averaged for each respondent. The results from this subset of NNPAS respondents were weighted using a specific set of sample weights to ensure the consumption data were representative of the Australian population. Mean consumption data are generally reported in grams/kg bw/day for the whole population aged 2 years

and above, where each individual's consumption of a commodity is divided by their own body weight before the summary population statistics are derived.

If no consumption was recorded for a food commodity in the nutrition survey, a default value of 0.0001 g/kg bw/day was assigned, except in the case of edible vegetable oils, where 'market share' data from Euromonitor 2016¹ was used to estimate the consumption. The percentage of market share data from Euromonitor for 'other vegetable oils' was used to calculate a percentage of the total consumption of vegetable oils.

#### 5.2 NESTI calculation

NESTI calculations use food consumption data at the 97.5<sup>th</sup> percentile only for consumers of the food of interest, based on a single day using 24-hour recall data from the 2011-12 NNPAS.

Consumption data were also derived from the subset of survey respondents with two days of 24-hour recall data. However, in this case the two days of recall data were pooled. This means the second day of recall data for each respondent was treated as a separate respondent, giving a larger number of total respondents (n=15470) with a single day of food recall data. The 97.5<sup>th</sup> percentile of consumption represents a high consumer of the particular food commodity from a single meal or over a 24-hour period, and is also termed the 'large portion'.

ARfDs for chemicals may be set for specific population sub-groups where necessary. Therefore, large portion food consumption data was derived for three population sub-groups: the entire population aged two years and above; children aged 2–6 years; and women of childbearing age (16–44 years).

<sup>&</sup>lt;sup>1</sup> Euormonitor is a market research database that provides detailed data and analysis on industries, economies, countries and consumers across 781 cities in 210 countries. Further information can be found at <a href="https://www.euromonitor.com/">https://www.euromonitor.com/</a>

## 6. Results of assessment

For all MRLs proposed in M1017, the dietary exposure estimates are at or below the relevant HBGVs, indicating that the residues pose negligible health and safety concerns to Australian consumers. The proposed MRL changes, origin of requests, comparisons with Codex MRLs and the dietary exposure estimates for the Australian population are listed in Table 1. Summaries of dietary exposure assessments for the proposed *All other foods except animal food commodities* MRLs for all chemicals considered are set out in the Appendix to this document. The Interpretive Guide (Figure 1) is only an **example** that provides relevant information to assist with interpreting Table 1.

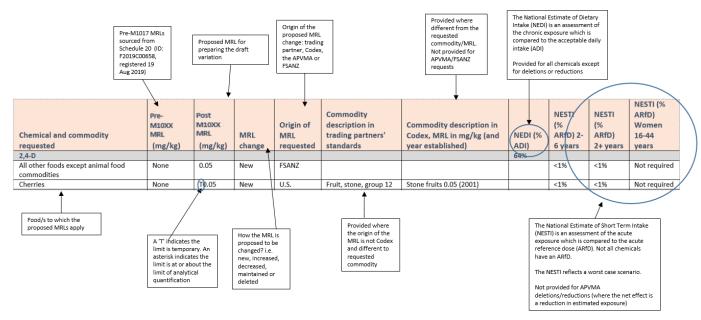


Figure 1: Interpretive guide to the proposed MRL changes

Table 1: Requested and approved MRLs for the various commodities and their dietary exposure estimates<sup>2</sup>

able 1. Requested and ap	pioved win	LS IOI II	ie various	Commod	ines and men c	iletaty exposure estili	iales			
Chemical and commodity requested	Pre- M1017 MRL (mg/kg)	Post M1017 MRL (mg/kg)	MRL change	Origin of MRL requested	Commodity description in trading partners' standards	Commodity description in Codex, MRL in mg/kg (and year established)	NEDI (% ADI) <sup>3</sup>	NESTI (% ARfD) 2- 6 years	NESTI (% ARfD) 2+ years	NESTI (% ARfD) Women 16-44 years
Abamectin							42%			
Coriander (leaves, stem, roots)	T0.5⁴	None	Deleted	APVMA				Not required	Not required	
Herbs	T0.5	None	Deleted	APVMA				Not required	Not required	
Kaffir lime leaves	T0.5	None	Deleted	APVMA				Not required	Not required	
Lemon grass	T0.5	None	Deleted	APVMA				Not required	Not required	
Pome fruit	0.01	0.02	Increased	U.S.	Fruit, pome, group 11-10	Pome fruits 0.01 (2016)		86%	25%	Not required
Acephate							99%			
Peanut	None	0.2	New	U.S.	Peanut	Commodity not listed		<1%	<1%	Not required
Acequinocyl							10%			
Hops, dry	4	15	Increased	U.S.	Hop, dried cones	Commodity not listed		Not required	Not required	Not required
Benzovindiflupyr							4%	·	·	
Pome fruit	None	0.2	New	U.S.	Fruit, pome, group 11-10	Pome fruits 0.2 (2017)		17%	5%	Not required
Boscalid							64%			
Chervil	T30	None	Deleted	APVMA				Not required	Not required	Not required
Coriander (leaves, roots and stems)	T30	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T30	None	Deleted	APVMA				Not required	Not required	Not required
Currants, black, red, white	None	15	New	EU	Currants (black, red and white)	Berries and other small fruits 10 (2010)		Not required	Not required	Not required

Note changes to residue definitions for Clothianidin and Thiamethoxam are not included in this table.
 The %ADI includes existing commodities listed in schedule 20 permitted to contain the chemical, not just the requested commodity(s).

<sup>&</sup>lt;sup>4</sup> The symbol 'T' indicates that the MRL is a temporary MRL

Chemical and commodity requested	Pre- M1017 MRL (mg/kg)	Post M1017 MRL (mg/kg)	MRL change	Origin of MRL requested	Commodity description in trading partners' standards	Commodity description in Codex, MRL in mg/kg (and year established)	NEDI (% ADI) <sup>3</sup>	NESTI (% ARfD) 2- 6 years	NESTI (% ARfD) 2+ years	NESTI (% ARfD) Women 16-44 years
Buprofezin							Not required			
Chervil	T50	None	Deleted	APVMA				Not required	Not required	Not required
Coriander (leaves, stems, roots)	T50	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T50	None	Deleted	APVMA				Not required	Not required	Not required
Mizuna	T50	None	Deleted	APVMA				Not required	Not required	Not required
Rucola [Rocket]	T50	None	Deleted	APVMA				Not required	Not required	Not required
Carbendazim							15%			
Strawberry	None	1	New	Codex		Berries and other small fruits (except grapes) 1 (2006)		14%	4%	Not required
Chlorothalonil							45%			
Peanut	0.2	0.3	Increased	U.S.	Peanut	Peanut 0.1 (2011)		<1%	<1%	Not required
Clofentezine							18%			
Stone fruits [except plums]	0.1	1	Increased	U.S.	Apricot Peach, subgroup 12- 12B	Stone fruits 0.5 (2008)		Not required	Not required	Not required
Clothianidin							12%			
Wine-grapes	*0.02 <sup>5</sup>	0.07	Increased	APVMA				1%	1%	Not required
Cypermethrin							Not required			
Coriander (leaves, stem, roots)	T5	None	Deleted	APVMA				Not required	Not required	Not required
Coriander, seed	T1	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T5	None	Deleted	APVMA				Not required	Not required	Not required
Lemon balm	T5	None	Deleted	APVMA				Not required	Not required	Not required
Parsley	None	T5	New	APVMA				Not required	Not required	Not required

 $<sup>^{5}</sup>$  An asterisk (\*) indicates that the maximum residue limit is set at the limit of determination

Chemical and commodity requested	Pre- M1017 MRL (mg/kg)	Post M1017 MRL (mg/kg)	MRL change	Origin of MRL requested	Commodity description in trading partners' standards	Commodity description in Codex, MRL in mg/kg (and year established)	NEDI (% ADI) <sup>3</sup>	NESTI (% ARfD) 2- 6 years	NESTI (% ARfD) 2+ years	NESTI (% ARfD) Women 16-44 years
Cyproconazole							Not required			
Pulses [except chickpea (dry); lentil (dry)]	T0.07	None	Deleted	APVMA				Not required	Not required	Not required
Deltamethrin							71%			
Strawberry	None	0.2	New	EU	Berries and small fruits, Strawberry	Strawberry 0.2 (2004)		3%	<1%	Not required
Difenoconazole							67%			
Strawberry	0.4	2	Increased	EU	Berries and small fruits, Strawberry	Strawberry 2 (2018)		5%	1%	Not required
Dimethomorph							9%			
Strawberry	None	0.7	New	EU	Berries and small fruits, Strawberry	Strawberry 0.5 (2015)		1%	<1%	Not required
Dithiocarbamates							Not required			
Herbs [except Parsley]	T5	None	Deleted	APVMA				Not required	Not required	Not required
Basil	None	T5	New	APVMA				Not required	Not required	Not required
Emamectin							Not required		·	
Bergamot	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Coriander (leaves, stem, roots)	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Coriander seed	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Dill seed	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Fennel seed	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Kaffir lime leaves	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Lemon grass	T0.05	None	Deleted	APVMA				Not required	Not required	Not required

	Pre- M1017	Post M1017		Origin of	Commodity description in	Commodity description in		NESTI	NESTI (%	NESTI (% ARfD) Women
Chemical and commodity	MRL	MRL	MRL	MRL	trading partners'	Codex, MRL in mg/kg (and	NEDI	ARfD) 2-	ARfD)	16-44
requested	(mg/kg)	(mg/kg)	change	requested	standards	year established)	(% ADI) <sup>3</sup>	6 years	2+ years	years
Lemon verbena (fresh weight)	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Salad burnett	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Endosulfan							3%			
Cocoa bean	None	0.2	New	Codex		Cocoa bean 0.2 (2007)		2%	1%	Not required
Etridiazole							Not required			
Beetroot	*0.02	None	Deleted	APVMA				Not required	Not required	Not required
Cotton seed	*0.02	None	Deleted	APVMA				Not required	Not required	Not required
Peanut	*0.02	None	Deleted	APVMA				Not required	Not required	Not required
Vegetables [except as otherwise listed under this chemical]	0.2	None	Deleted	APVMA				Not required	Not required	Not required
Fenazaquin							5%			
Citrus fruits	None	0.4	New	U.S.	Fruit, Citrus, Group 10-10	Commodity not listed		23%	8%	Not required
Grapes, dried (raisins)	None	0.8	New	U.S.	Grape, raisin	Commodity not listed		4%	<1%	Not required
Grapes (except dried)/ Berries and other small fruits	None	0.7	New	U.S.	Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	Commodity not listed		13%	19%	Not required
Hops, dry	None	30	New	U.S.	Hop, dried cones	Hops, dry		3%	2%	Not required
Stone fruits	None	2	New	U.S.	Fruit, stone, group 12-12	Commodity not listed		61%	22%	Not required
Legume vegetables	None	0.4	New	U.S.	Vegetable, legume, edible podded, subgroup 6A	Commodity not listed		2%	<1%	Not required
Fenhexamid							Not required			
Chervil	T15	None	Deleted	APVMA				Not required	Not required	Not required
Coriander (leaves, stems and roots)	T15	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T15	None	Deleted	APVMA				Not required	Not required	Not required

										NESTI
	Pre-	Post			Commodity			NESTI	NESTI	(% ARfD)
	M1017	M1017		Origin of	description in	Commodity description in		(%	(%	Women
Chemical and commodity	MRL	MRL	MRL	MRL	trading partners'	Codex, MRL in mg/kg (and	NEDI	ARfD) 2-	ARfD)	16-44
requested	(mg/kg)	(mg/kg)	change	requested	standards	year established)	(% ADI) <sup>3</sup>	6 years	2+ years	years
Mizuna	T15	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Rucola [Rocket]	T15	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Fenoxycarb							Not			
							required			
Currant, black	T2	None	Deleted	APVMA				Not	Not	Not required
Currant, red	T2	Ness	Deleted	A D) (A 4 A				required	required Not	Not assissed
Currant, red	12	None	Deleted	APVMA				Not required	required	Not required
Gooseberry	T2	None	Deleted	APVMA				Not	Not	Not required
dooseberry	12	None	Deleteu	APVIVIA				required	required	Not required
Fentin							Not	required	required	
							required			
Cacao beans [cocoa beans]	*0.1	None	Deleted	APVMA				Not	Not	Not required
•								required	required	
Carrot	0.2	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Celeriac	0.1	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Celery	1	None	Deleted	APVMA				Not	Not	Not required
		1						required	required	
Coffee beans	*0.1	None	Deleted	APVMA				Not	Not	Not required
Danasit	*0.05	Ness	Deleted	APVMA				required	required Not	Not assissed
Peanut	*0.05	None	Deleted	APVIVIA				Not required	required	Not required
Pecan	*0.05	None	Deleted	APVMA				Not	Not	Not required
recarr	0.05	None	Deleted	AI VIVIA				required	required	Not required
Potato	0.1	None	Deleted	APVMA				Not	Not	Not required
		1						required	required	
Rice	*0.1	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Sugar beet	0.2	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Flazasulfuron							<1%			
Almonds	None	0.01	New	U.S.				Not	Not	Not required
								required	required	

	Pre- M1017	Post M1017		Origin of	Commodity description in	Commodity description in		NESTI (%	NESTI	NESTI (% ARfD) Women
Chemical and commodity	MRL	MRL	MRL	MRL	trading partners'	Codex, MRL in mg/kg (and	NEDI	ARfD) 2-	ARfD)	16-44
requested	(mg/kg)	(mg/kg)	change	requested	standards	year established)	(% ADI) <sup>3</sup>	6 years	2+ years	years
Flonicamid							14%			
Hops, dry	7	20	Increased	U.S.	Hop, dried cones	Hops, dry 20 (2016)		Not required	Not required	Not required
Fluazifop-p-butyl							Not required			
Herbs	T2	None	Deleted	APVMA				Not required	Not required	Not required
Parsley	None	T2	New	APVMA				Not required	Not required	Not required
Fluopicolide							24%			
Hops, dry	None	15	New	U.S.	Hop, dried cones	Commodity not listed		Not required	Not required	<1%
Fluopyram							81%			
Citrus fruits	None	1	New	U.S.	Fruit, citrus, group 10-10	Mandarins, subgroup of (including mandarin-like hybrids)(includes all commodities in this subgroup) 0.6 (2018)		11%	4%	Not required
Potato	0.03	0.1	Increased	U.S.	Vegetable, tuberous and corm, subgroup 1C	Potato 0.15 (2018)		<1%	<1%	Not required
Peanuts	0.09	0.2	Increased	U.S.	Peanut	Peanut 0.2 (2018)		<1%	<1%	Not required
Raspberries, red, black	3	5	Increased	EU	Berries and small fruits, cane fruits, raspberries (red and yellow)	Cane berries 5 (2018)		5%	<1%	Not required
Currants, black, red, white	None	7	New	EU	Berries and small fruits, other berries and small fruits, currants	Commodity not listed		9%	2%	Not required
Folpet							<1%			
Strawberry	None	T5	New	EU	Berries and small fruits, Strawberry	Strawberry 5 (2006)		Not required	Not required	5%
Halosulfuron-methyl							2%			
Almonds	None	0.05	New	U.S.	Nut, tree, group 14	Chemical not listed		Not required	Not required	Not required
Eggs	None	*0.01	New	APVMA				Not required	Not required	Not required

Chemical and commodity requested  Hexythiazox	Pre- M1017 MRL (mg/kg)	Post M1017 MRL (mg/kg)	MRL change	Origin of MRL requested	Commodity description in trading partners' standards	Commodity description in Codex, MRL in mg/kg (and year established)	NEDI (% ADI) <sup>3</sup> 20%	NESTI (% ARfD) 2- 6 years	NESTI (% ARfD) 2+ years	NESTI (% ARfD) Women 16-44 years
Hops, dry	2	20	Increased	U.S.	Hop, dried cones	Hops, dry 3 (2012)		Not	Not	Not required
Imidacloprid							Not required	required	required	
Coriander (leaves, stem, roots)	T5	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T5	None	Deleted	APVMA				Not required	Not required	Not required
Kaffir lime leaves	T5	None	Deleted	APVMA				Not required	Not required	Not required
Lemon balm	T5	None	Deleted	APVMA				Not required	Not required	Not required
Lemon grass	T5	None	Deleted	APVMA				Not required	Not required	Not required
Mizuna	T5	None	Deleted	APVMA				Not required	Not required	Not required
Rose and dianthus (edible flowers)	T5	None	Deleted	APVMA				Not required	Not required	Not required
Tumeric root	T0.05	None	Deleted	APVMA				Not required	Not required	Not required
Indoxacarb							Not required			
Coriander (leaves, roots and stems)	T20	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T20	None	Deleted	APVMA				Not required	Not required	Not required
Lemon balm	T10	None	Deleted	APVMA				Not required	Not required	Not required
Mexican Tarragon	T20	None	Deleted	APVMA				Not required	Not required	Not required
Iprodione							79%			
Grapes	20	60	Increased	U.S.	Grape	Grapes 10 (not specified)		Not required	Not required	Not required

Chemical and commodity requested  Metalaxyl	Pre- M1017 MRL (mg/kg)	Post M1017 MRL (mg/kg)	MRL change	Origin of MRL requested	Commodity description in trading partners' standards	Commodity description in Codex, MRL in mg/kg (and year established)	NEDI (% ADI) <sup>3</sup>	NESTI (% ARfD) 2- 6 years	NESTI (% ARfD) 2+ years	NESTI (% ARfD) Women 16-44 years
Cacao beans	None	0.2	New	Codex		Cacao beans 0.2 (1991)		Not required	Not required	Not required
Hops, dry	10	20	Increased	U.S.	Hop, dried cones	Hops, dry 10 (not specified)		Not required	Not required	Not required
Strawberry	T0.5 (included in Berries and other small fruits)	0.6	Increased	EU	Berries and small fruits, Strawberry	Commodity not listed		Not required	Not required	Not required
Methoxyfenozide							Not required			
Coriander (leaves, stems and roots)	T20	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T20	None	Deleted	APVMA				Not required	Not required	Not required
Mexican tarragon	T20	None	Deleted	APVMA				Not required	Not required	Not required
Rucola [Rocket]	T20	None	Deleted	APVMA				Not required	Not required	Not required
Myclobutanil							Not required	'	,	
Chervil	T2	None	Deleted	APVMA				Not required	Not required	Not required
Coriander (leaves, stem and roots)	T2	None	Deleted	APVMA				Not required	Not required	Not required
Herbs	T2	None	Deleted	APVMA				Not required	Not required	Not required
Mizuna	T2	None	Deleted	APVMA				Not required	Not required	Not required
Rucola [rocket]	T2	None	Deleted	APVMA				Not required	Not required	Not required
Oxathiapiprolin							<1%			
Blackberry	None	0.5	New	U.S.	Caneberry subgroup 13-07A			Not required	Not required	Not required
Raspberry, red, black	None	0.5	New	U.S.	Caneberry subgroup 13-07A	Cane berries 0.5 (Adopted by Codex Alimentarius Commission 2019)		Not required	Not required	Not required

	Pre-	Post			Commodity			NESTI	NESTI	NESTI (% ARfD)
	M1017	M1017		Origin of	description in	Commodity description in		(%	(%	Women
Chemical and commodity	MRL	MRL	MRL	MRL	trading partners'	Codex, MRL in mg/kg (and	NEDI	ARfD) 2-	ARfD)	16-44
requested	(mg/kg)	(mg/kg)	change	requested	standards	year established)	(% ADI) <sup>3</sup>	6 years	2+ years	years
Pendimethalin							Not required			
Herbs	*0.05	None	Deleted	APVMA				Not required	Not required	Not required
Parsley	None	T*0.05	New	APVMA				Not required	Not required	Not required
Phosmet							88%			
Stone Fruits (except cherries)	None	5	New	U.S.	Peaches, nectarines, apricots, plum	Apricot 10 (2008), Peach 10 (1999), Nectarine 10 (2008), Plum commodity not listed		77%	29%	Not required
Phosphorous acid <sup>6</sup>							Not required			
Herbs	T150	None	Deleted	APVMA				Not required	Not required	Not required
Kaffir lime leaves	T150	None	Deleted	APVMA				Not required	Not required	Not required
Lemon balm	T150	None	Deleted	APVMA				Not required	Not required	Not required
Lemon grass	T150	None	Deleted	APVMA				Not required	Not required	Not required
Lemon verbena	T150	None	Deleted	APVMA				Not required	Not required	Not required
Rose and dianthus (edible flowers)	T150	None	Deleted	APVMA				Not required	Not required	Not required
Basil	None	T150	New	APVMA				Not required	Not required	Not required
Fennel, leaf	None	T150	New	APVMA				Not required	Not required	Not required
Parsley	None	T150	New	APVMA				Not required	Not required	Not required
Propiconazole							23%			
Anise myrtle leaves	T10	None	Deleted	APVMA				Not required	Not required	Not required

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<sup>&</sup>lt;sup>6</sup> In 2001 the TGA advised the APVMA "In view of the nature of the chemical and its pattern of use, application method and rates, and the nature of the potential residues, its impact on public health should be negligible. MRLs are established as there is a need to monitor the agricultural contribution of Phosphorous acid in foods and for trade purposes.

	Pre-	Post			Commodity			NESTI	NESTI	NESTI (% ARfD)
	M1017	M1017		Origin of	description in	Commodity description in		(%	(%	Women
Chemical and commodity	MRL	MRL	MRL	MRL	trading partners'	Codex, MRL in mg/kg (and	NEDI	ARfD) 2-	ARfD)	16-44
requested	(mg/kg)	(mg/kg)	change	requested	standards	year established)	(% ADI) <sup>3</sup>	6 years	2+ years	vears
Chervil	T10	None	Deleted	APVMA	Staridards	year established)	(/0/151)	Not	Not	Not required
	1							required	required	
Coriander (leaves, roots and stems)	T10	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Herbs [except Parsley]	T10	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Lemon balm	T10	None	Deleted	APVMA				Not	Not	Not required
Lemon myrtle leaves	T10	None	Deleted	APVMA				required Not	required Not	Not required
Lemon myrtie leaves	110	None	Deleted	APVIVIA				required	required	Not required
Mizuna	T10	None	Deleted	APVMA				Not	Not	Not required
24.14	. 20	1.10	Deleted	7 7				required	required	
Rucola [rocket]	T10	None	Deleted	APVMA				Not	Not	Not required
								required	required	-
Stone fruit [except plum]	2	4	Increased	U.S.	Fruit, stone, group	Cherry 4 (Adopted by Codex		41%	15%	Not required
					12-12, except plum	Alimentarius Commission				
0.1						2019), Peach 5 (2014)	B1 - 1			
Quinoxyfen							Not required			
Chervil	T5	None	Deleted	APVMA			required	Not	Not	Not required
CHEIVII	.5	None	Deleted	7.1 7.17.1				required	required	Notrequired
Coriander (leaves, roots and stems)	T5	None	Deleted	APVMA				Not	Not	Not required
, ,								required	required	
Herbs	T5	None	Deleted	APVMA				Not	Not	Not required
								required	required	
Mizuna	T5	None	Deleted	APVMA				Not	Not	Not required
D. sala [Dashat]	T5	NI	Balana	A D) (8 4 A				required	required	<b>NI-1</b>
Rucola [Rocket]	15	None	Deleted	APVMA				Not required	Not required	Not required
Sethoxydim							63%	required	required	
Almonds	None	0.2	New	U.S.	Nut, tree, group 14	Chemical not listed	3370	Not	Not	Not required
		1			, , , , , , , , , , , , , , , , , , , ,			required	required	
Tebuconazole							Not required		·	
Chervil	T0.5	None	Deleted	APVMA				Not	Not	Not required
								required	required	<u> </u>
Coriander (leaves, roots and stems)	T0.5	None	Deleted	APVMA				Not	Not	Not required
								required	required	

Chemical and commodity requested	Pre- M1017 MRL (mg/kg)	Post M1017 MRL (mg/kg)	MRL change	Origin of MRL requested	Commodity description in trading partners' standards	Commodity description in Codex, MRL in mg/kg (and year established)	NEDI (% ADI) <sup>3</sup>	NESTI (% ARfD) 2- 6 years	NESTI (% ARfD) 2+ years	NESTI (% ARfD) Women 16-44 years
Herbs	T0.5	None	Deleted	APVMA				Not required	Not required	Not required
Lemon balm	T0.5	None	Deleted	APVMA				Not required	Not required	Not required
Mizuna	T0.5	None	Deleted	APVMA				Not required	Not required	Not required
Rucola [rocket]	T0.5	None	Deleted	APVMA				Not required	Not required	Not required
Tebuthiuron							Not required	·	·	
Sugar cane	T0.2	None	Deleted	APVMA			-	Not required	Not required	Not required
Tetraconazole							25%	·	·	
Currants, black, red, white	None	0.2	New	EU	Berries and small fruits, other berries and small fruits, currants (black, red, white)	Chemical not listed		2%	2%	Not required
Triadimenol							12%			
Anise myrtle leaves (dried)	None	T0.05	New	APVMA				<1%	<1%	Not required
Lemon myrtle leaves (dried)	None	T0.05	New	APVMA				<1%	<1%	Not required
Trifloxystrobin							23%			
Currants, black, red, white	1.5	3	Increased	EU	Berries and small fruits, other berries and small fruits, currants (black, red, white)	Commodity not listed		Not required	Not required	Not required

# 6.1 Appendix – Dietary exposure assessment summaries for the proposed All other foods except animal food commodities MRLs

All assessments for the chemicals considered follow the principles for establishing *All other* foods except animal food commodities MRLs as set out by FSANZ in 2016<sup>1</sup>.

This appendix relates to all chemicals requested for inclusion in proposal M1017. It should be noted that not all the requested chemicals progressed to the stage of dietary exposure estimates during the risk assessment process and therefore some requested chemicals were not included in the draft Amendment. Chemicals excluded from M1017 may still be listed in this appendix to indicate that they were also not considered for establishment of an *All other foods except animal food commodities* MRL or indicate that a review of an existing *All other foods except animal food commodities* MRL was conducted.

It is important to note that if the registered use of a chemical on a specific commodity is proposed to be removed from schedule 20 (for example, by the APVMA) and a previous harmonisation MRL request for that commodity/chemical combination has been received, the commodity and MRL will remain in schedule 20. Similarly, if a chemical is being deleted from the APVMA MRL Standard, and previous harmonisation requests for the chemical have been received, these will also remain in schedule 20.

However, if a chemical had a registered use in Australia and FSANZ had established an *All other foods except animal food commodities* MRL and the chemical has subsequently been removed from schedule 20, the *All other foods except animal food commodities* MRL will also be removed. Any MRL for specific commodities included in schedule 20 under a harmonisation request for that chemical will remain in schedule 20 (unless other considerations warrant them being removed or amended).

For the consideration of *All other foods except animal food commodities* MRLs, FSANZ has assumed in the National Estimate of Dietary Intake (NEDI) calculations that 10% of this consumption amount would be likely to contain residues. This assumption does not apply to calculations of the National Estimated Short-Term Dietary Intake (NESTI).

The relevant Health Based Guidance Values for the NEDI and NESTI are the Acceptable Dietary Intake (ADI) and the Acute Reference Dose (ARfD) respectively.

## Table of contents

Abamectin	22
Acephate	22
Acequinocyl	
Benzovindiflupyr	
Boscalid	
Buprofezin	
Carbendazim	
Chlorothalonil	
Clethodim	
Clofentezine	
Clothianidin	
Cypermethrin	
Cyproconazole	

Deitamethrin	_
Difenoconazole	
Dimethomorph	
Dithiocarbamates	_
Emamectin	
Endosulfon	
Etridiazole	
Fenazaquin	24
Fenhexamid	
Fenoxycarb	24
Fentin	24
Flazasulfuron	24
Flonicamid	24
Fluazifop-p-butyl	24
Fluopicolide	
Fluopyram	
Folpet	
Halosulfuron-methyl	
Haloxyfop	
Hexythiazox	25
Imidacloprid	
Indoxacarb	
Iprodione	
Metalaxyl	
Metalaxyl-M (Mefenoxam)	
Methoxyfenozide	
Myclobutanil	
Oxathiapiprolin	
Pendimethalin	
Phosmet	26
Phosphorous acid	
Propiconazole	
Quinoxyfen	
Sethoxydim	
Tebuconazole	
Tebuthiuron	
Tetraconazole	
Thiamethoxam	
Triadimenol	
Trifloxystrobin	27

#### Abamectin

An MRL of 0.01 mg/kg for *All other foods except animal food commodities* for abamectin is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## **Acephate**

Acephate was excluded from consideration of an *All other foods except animal food commodities* MRL because the NEDI from existing permissions is >80% of the ADI.

## Acequinocyl

Acequinocyl was excluded from consideration of an *All other foods except animal food commodities* MRL as there is no registered use of acequinocyl in Australia.

## Benzovindiflupyr

Benzovindiflupyr was excluded from consideration of an *All other foods except animal food commodities* MRL as there is no registered use of benzovindiflupyr in Australia.

#### **Boscalid**

An MRL of 0.5 mg/kg for *All other foods* for boscalid is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## **Buprofezin**

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for buprofezin is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Carbendazim

Carbendazim was excluded from consideration of an *All other foods except animal food commodities* MRL as it is a schedule 7 only poison.

#### Chlorothalonil

Chlorothalonil has been nominated and prioritised for review by the APVMA and is therefore excluded from consideration of an *All other foods except animal food commodities* MRL as per the principles established in P1027.

#### Clethodim

Residues arising from the use of Clethodim are covered by the MRLs for Sethoxydim.

#### Clofentezine

An MRL of 0.02 mg/kg for *All other foods* for clofentezine is currently listed in Schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Clothianidin

The current *All other foods except animal food commodities* MRL of 0.02 mg/kg has been temporarily increased to T0.1 by the APVMA as part of their routine process and is listed in schedule 20. MRL was reviewed as part of M1017 and therefore no change is proposed.

## Cypermethrin

An MRL of \*0.01 mg/kg for *All other foods* for cypermethrin has been established by the APVMA and is listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## Cyproconazole

An MRL of 0.01 mg/kg for *All other foods except animal food commodities* for cyproconazole is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Deltamethrin

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for deltamethrin is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Difenoconazole

An MRL of 0.02 mg/kg for *All other foods except animal food commodities* for difenoconazole is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Dimethomorph

An MRL of 0.2 mg/kg for *All other foods except animal food commodities* for dimethomorph is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Dithiocarbamates**

Dithiocarbamates were excluded from consideration of an *All other foods except animal food commodities* MRL because the NEDI from existing permissions is >80% of the ADI.

#### **Emamectin**

An MRL of 0.005mg/kg for *All other foods except animal food commodities* is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Endosulton**

Endosulfon was excluded from consideration of an *All other foods except animal food commodities* MRL as there is no registered use of endosulfon in Australia.

#### **Etridiazole**

It was not considered appropriate at this time to establish an *All other foods except animal food commodities* MRL based on the APVMA's proposed deletion of all permitted uses of etridiazole in Australia. Therefore no *All other foods except animal food commodities* MRL is proposed.

## Fenazaquin

Fenazaquin was excluded from consideration of an *All other foods except animal food commodities* MRL as there is no registered use of fenazaquin in Australia.

#### **Fenhexamid**

An MRL of 0.1 mg/kg for *All other foods except animal food commodities* for fenhexamid is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## **Fenoxycarb**

An MRL of 0.1 mg/kg for *All other foods except animal food commodities* for fenoxycarb is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Fentin**

It was not considered appropriate at this time to establish an *All other foods except animal food commodities* MRL based on the APVMA's proposed deletion of permitted uses of fentin in Australia. Therefore no *All other foods except animal food commodities* MRL is proposed.

## **Flazasulfuron**

Flazasulfuron was excluded from consideration of an *All other foods except animal food commodities* MRL as it is not listed in schedule 20, there are no registered uses of flazasulfuron in Australia.

#### **Flonicamid**

An MRL of 0.2 mg/kg for *All other foods except animal food commodities* for flonicamid is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## Fluazifop-p-butyl

An MRL of 0.02 mg/kg for *All other foods except animal food commodities* for fluazifop-p-butyl is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Fluopicolide

An MRL of 0.01 mg/kg for *All other foods* for fluopicolide has been established by the APVMA and is listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Fluopyram**

An MRL of 0.1 mg/kg for *All other foods except animal food commodities* for fluopyram is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## **Folpet**

Folpet was excluded from consideration of an *All other foods except animal food commodities* MRL as there is no registered use of Folpet in Australia.

## Halosulfuron-methyl

An *All other foods except animal food commodities* MRL for Halosulfuron-methyl could not be established as even at the LOD, the contribution of *All other foods except animal food commodities* to total dietary exposure exceeded the 20% target. Consequently, there was no MRL that was practical. Therefore no *All other foods except animal food commodities* MRL is proposed.

## Haloxyfop

Haloxyfop was excluded from consideration of an *All other foods except animal food commodities* MRL because the NEDI from existing permissions (using the APVMA HBGV) is >80% ADI. FSANZ did consider an *All other foods except animal food commodities* MRL for haloxyfop using the JMPR HBGV. However, even at the lowest practical limit, the contribution to the total dietary exposure exceeded the 20% target. Therefore based on the current permissions, an *All other foods except animal food commodities* MRL could not be established.

## Hexythiazox

An MRL of 0.05mg/kg for *All other foods except animal food commodities* for hexythiazox is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## **Imidacloprid**

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for imidacloprid is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Indoxacarb

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for indoxacarb is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Iprodione**

An MRL of 0.1 mg/kg for *All other foods except animal food commodities* for iprodione is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Metalaxyl

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for metalaxyl is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## Metalaxyl-M (Mefenoxam)

See metalaxyl

## Methoxyfenozide

An MRL of 0.03 mg/kg for *All other foods except animal food commodities* for methoxyfenozide is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## Myclobutanil

An *All other foods except animal food commodities* MRL for myclobutanil is currently listed in schedule 20. Based on the APVMA's proposed deletions or reduction of permitted uses of myclobutanil in Australia this MRL was reviewed as part of M1017 and no change is proposed.

## Oxathiapiprolin

An MRL of 0.02 mg/kg for *All other foods except animal food commodities* for oxathiapiprolin is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Pendimethalin**

An MRL of 0.02 mg/kg for *All other foods except animal food commodities* for pendimethalin is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Phosmet**

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for phosmet is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## Phosphorous acid

MRLs are established for phosphorous acid as there is a need to monitor the agricultural contribution of phosphorous acid in foods and for trade purposes. However, HBGVs are not established for phosphorous acid, therefore a DEA has not been done and consequently, phosphorous acid was excluded from consideration of an AoF MRL.

#### **Propiconazole**

An MRL of 0.05mg/kg for *All other foods except animal food commodities* is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### Quinoxyfen

An MRL of 0.02 mg/kg for *all other foods except animal food commodities* for quinoxyfen is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## Sethoxydim

An MRL of 0.1mg/kg for *All other foods except animal food commodities* is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Tebuconazole**

An MRL of 0.05mg/kg for *All other foods except animal food commodities* is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Tebuthiuron**

It was not considered appropriate at this time to establish an *All other foods except animal food commodities* MRL based on the APVMA's proposed deletion of all plant MRLs as part of M1017. Therefore no *All other foods except animal food commodities* MRL is proposed.

#### **Tetraconazole**

An MRL of 0.02 mg/kg for *All other foods except animal food commodities* for tetraconazole is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

#### **Thiamethoxam**

The current *All other foods except animal food commodities* MRL of 0.02 mg/kg has been temporarily increased to T0.5 by the APVMA as part of their routine process and is listed in schedule 20. This MRL was not reviewed as part of M1017 and therefore no change is proposed.

#### **Triadimenol**

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for triadimenol is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.

## **Trifloxystrobin**

An MRL of 0.05 mg/kg for *All other foods except animal food commodities* for trifloxystrobin is currently listed in schedule 20. This MRL was reviewed as part of M1017 and no change is proposed.