Proposals to Amend (No. 2) the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2011

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BIOSECURITY NEW ZEALAND

NEW ZEALAND FOOD SAFETY AUTHORITY

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Submissions

The Ministry of Agriculture and Forestry (MAF) – that now incorporates the New Zealand Food Safety Authority (NZFSA) - invites public comment on this discussion document which outlines **proposals to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2011**.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section in the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Where possible, reasons and data to support comments are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- The title of the discussion document;
- Your name and title (if applicable);
- Your organisation's name (if applicable); and
- Your address.

Please submit your response by 5:00pm on Monday 18 June 2012. Your comments should be sent to:

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The Official Information Act

The Official Information Act 1982 (the OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MAF will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

1. INTRODUCTION

Maximum residue limits (MRLs) are the maximum legal limits for residues of agricultural compounds and veterinary medicines in food for sale in New Zealand. MRLs are primarily a tool for monitoring the use of agricultural compounds in accordance with good agricultural practice (GAP). GAP is not explicitly defined or regulated, but is the generally accepted means for producing safe primary produce in a particular location while taking account of climate, pests or diseases and other environmental factors. MRLs are used to minimise risks to public health by ensuring that chemical residues in food are as low as practicable, without compromising the ability of the chemical to successfully do what is intended.

1.1. BACKGROUND

MRLs are set out in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards (the MRL Standards). The MRL Standards are amended a number of times each year to reflect changes in the use of agricultural compounds in the production of food. The MRL Standards 2011 are on the MAF Foodsafety website at: http://www.foodsafety.govt.nz/elibrary/industry/NZ-MRL-of-Agricultural-Compounds-Food-Standards-2011.pdf

MAF administers the MRL Standards, but the final decision on any changes to the MRL Standards rests with the Minister for Food Safety. Under section 11E and 11L of the Food Act 1981, when amending or issuing the MRL Standards, the Minister must take into account the following:

- The need to protect public health;
- The desirability of avoiding unnecessary restrictions on trade;
- The desirability of maintaining consistency between New Zealand's food standards and those applying internationally;
- New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia-New Zealand Joint Food Standards Agreement; and
- Such other matters as the Minister considers appropriate.

Possible implications for public health are considered during the toxicological and dietary risk assessments, by comparing the estimated dietary intake with a Potential Daily Exposure (food) (PDE_{food}) or where there is no PDE_{food}, by comparing it with the Acceptable Daily Intake (ADI). PDE_{food} and ADI are described below.

A PDE_{food} or Potential Daily Exposure (food), is a value determined by a toxicological evaluation by Environmental Protection Authority (EPA) as part of its responsibilities under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act), which has some responsibility for managing public health.[1] A PDE_{food} gives the potential daily exposure a person may be subject to from a substance, via food. MAF uses a PDE_{food}, rather than the internationally-determined ADI, where a PDE_{food} is available, due to the HSNO Act in New Zealand. The ADI and PDE_{food} are largely equivalent, as they are determined using the same set of toxicology data and in a very similar scientific process.

An ADI or Acceptable Daily Intake is defined by the World Health Organization (WHO) as: "the daily intake which, during an entire lifetime, appears to be without appreciable risk on the basis of all the known facts at the time". "Without appreciable risk" has been further defined as: "the practical certainty that injury will not result even after a lifetime of

[1]The purpose of the HSNO Act 1996 is "to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms".

exposure". ADIs are established by the WHO and Food and Agriculture Organization of the United Nations (FAO) joint expert committees, made up of toxicologists and residue specialists. The ADI information from these joint committees also feeds into the Codex Alimentarius Commission (Codex), which sets international MRLs.

1.2. SUMMARY OF PROPOSED AMENDMENT

The proposed MRLs have been thoroughly assessed in accordance with international methodologies such as those utilised by the expert committees advising the Codex Alimentarius Commission (Codex). Information on the technical assessment of each proposal is included in this document (refer section 2) and covers the following:

- Rationale;
- Chemical information;
- Good agricultural practice (GAP);
- Residues information;
- Dietary risk assessment;
- Toxicological / public health assessment; and
- International MRLs.

MAF reviewed the estimated dietary exposure assessments for the application of the proposals in this discussion paper and has determined that the residues associated with the proposed MRLs do not present any public health and safety concerns.

New MRLs

MAF proposes to add the following new MRLs to the MRL Standards:

- 0.1mg/kg for etoxazole when used as a miticide on avocados;
- 0.02 mg/kg for fenbuconazole when used as a fungicide on pome fruit;
- 0.02mg/kg for proquinazid when used as a fungicide on grapes, 0.1mg/kg when used on apples or cucurbits (edible peel), and 0.01mg/kg when used on cucurbits (inedible peel).
-

MRL Exemptions

MAF proposes to exempt the following substance from the MRL Standards:

- Didecyl Dimethyl Ammonium Chloride when used as a fungicide on fruits and vegetables;
-

Other MRL Amendments

- MAF proposes to make these amendments to the following MRLs from the MRL Standards:
- Delete the MRL for azinphos-methyl on kiwifruit and change food type; fruits (except kiwifruit) to stonefruits and strawberry;
- Delete the MRL entries for baquiloprim, clopidol, 3,5-dinitro-o-toluamide, dichlofluanid, bioallethrin, bioresmethrin and fenbutatin oxide.

1.3. NEXT STEPS

Following the closing date for submissions **5:00pm on Friday 1 July 2011**, all submissions will be considered and analysed before a recommendation is made to the Minister for Food Safety, who makes the final decision on issuing any amendments to the MRL Standards.

If an amendment is agreed upon, it will be signed by the Minister for Food Safety and will come into force 28 days after being published in the *New Zealand Gazette.*

2. PROPOSALS

2.1. PROPOSAL TO SET AN MRL FOR ETOXAZOLE

It is proposed that an MRL is set for etoxazole when used on avocados. It is proposed that Schedule One of the MRL Standards be amended to include the following, and that this will be the resulting entry for etoxazole in Schedule One of the MRL Standards:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Etoxazole	153233-91-1	Etoxazole	Avocados	0.1

Amendment Rationale

The proposed MRL represents a new registration in New Zealand for the active ingredient etoxazole. The proposed MRL will manage the use of etoxazole as a miticide in avocados, to the application rates and withholding periods that are proposed as GAP in New Zealand.

Chemical Information

Common name of compound	Etoxazole
Use of compound	Miticide
Chemical Abstract Services (CAS) Registry number	153233-91-1
Type of compound	Diphenyl oxazoline
Administration method	Spray

Good Agricultural Practice (GAP)

Etoxazole is proposed for use as a miticide in avocados. Application is at a rate of 3.85 gai/100L etoxazole in 750 - 3000L water/ha (29–115.5gai/ha), made at first sign of mite crawlers.

Residues Information

The residue data for avocados supports a MRL of 0.1mg/kg for etoxazole when the last treatment is 14 days prior to harvest. An MRL of 0.1mg/kg is proposed to support GAP.

Dietary Risk Assessment

Potential Daily Exposure	0.105 mg/kg bw/day

The potential daily exposure via food (PDE_{food}) is used for dietary intake calculation where a value has been set.

The chronic dietary exposure to etoxazole is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for etoxazole is equivalent to less than 0.05% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological/Public Health Assessment

It has been determined that the use of etoxazole as a miticide in avocados according to GAP (specified above), is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
European Commission		
Etoxazole	Avocados	0.02*

Under clause 6(3)(b) of the MRL Standards imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications *Pesticide Residues in Food* or *Residues of Veterinary Drugs in Foods.*

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.2. PROPOSAL TO SET AN MRL FOR FENBUCONAZOLE

It is proposed that an MRL is set for fenbuconazole when used on pome fruits. It is proposed that Schedule One of the MRL Standards be amended to include the following, and that this will be the resulting entry for fenbuconazole in Schedule One of the MRL Standards:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Fenbuconazole	114369-43-6	Fenbuconazole	Pome fruits	0.02

Amendment Rationale

The proposed MRL represents a new registration in New Zealand for the active ingredient fenbuconazole. The proposed MRL will manage the use of fenbuconazole as a fungicide to control black spot and powdery mildew for pome fruits, to the application rates and withholding periods that are proposed as GAP in New Zealand.

Chemical Information

Common name of compound	Fenbuconazole
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	114369-43-6
Type of compound	Fungicide
Administration method	Spray

Good Agricultural Practice (GAP)

Fenbuconazole is proposed for use as a fungicide in pome fruits. Application is at a rate of 2.125 gai/100L fenbuconazole in 2000L water/ha (42.5 gai/ha) at 7 – 10 day intervals commencing at pink and continuing until 30 November.

Residues Information

The residue data for pome fruits supports a MRL of 0.02mg/kg for fenbuconazole when the last treatment is 10 weeks prior to harvest or after 30 November, which ever occurs first. An MRL of 0.02 mg/kg is proposed to support GAP.

Dietary Risk Assessment

Acceptable Daily Intake	0.006 mg/kg bw/day

The potential daily exposure via food (PDE_{food}) is used for dietary intake calculation where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE_{food}.

The chronic dietary exposure to fenbuconazole is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for fenbuconazole is equivalent to less than 1% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological / Public Health Assessment

It has been determined that the use of fenbuconazole as a fungicide for pome fruits according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
Codex Alimentarius		
Fenbuconazole	Pome fruits	0.1
European Commission		
Fenbuconazole	Apple	0.4
	Pear	0.2
Japan		
Fenbuconazole	Apple	1
	Pear	0.7

Under clause 6(3)(b) of the MRL Standards imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications *Pesticide Residues in Food* or *Residues of Veterinary Drugs in Foods*.

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.3. PROPOSAL TO SET AN MRL FOR PROQUINAZID

It is proposed that an MRL is set for proquinazid when used as a fungicide for grapes, apples and cucurbits. It is proposed that Schedule One of the MRL Standards be amended to include the following and that this will be the resulting entry for proquinazid in Schedule One of the MRL Standards

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Proquinazid	189278-12-4	Proquinazid	Grapes Apples Cucurbits(inedible peel) Cucurbits(edible peel)	0.02 0.1 0.01 0.1

Amendment Rationale

The proposed MRLs represent a new registration in New Zealand for the active ingredient proquinazid. The proposed MRL will manage the use of proquinazid as a fungicide to control powdery mildew in grapes, apples and cucurbits, to the application rates and withholding periods that are proposed as GAP in New Zealand.

Chemical Information

Common name of compound	Proquinazid
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	189278-12-4
Type of compound	Quinazolinone
Administration method	Spray

Good Agricultural Practice (GAP)

Proquinazid is proposed for use as a fungicide for grapes, apples and cucurbits. Application is at a rate of:

- Grapes - 25 ml/100litres minimum of 200ml/ha over flowering to 250ml/ha at bunch closure {40 - 50 gai/ha}
- Apples - 25 ml/100litres minimum 500ml/ha {2000 litres water/ha}{100 gai/ha}
- Cucurbits - 250 ml/ha {50 gai/ha}

Residues Information

Residue data for grapes, apples cucurbits (inedible peel) and cucurbits (edible peel) support MRLs of 0.02 mg/kg, 0.1 mg/kg, 0.01 mg/kg and 0.1 mg/kg consequently for proquinazid when the last treatment is:

- Grapes – At least 56 days prior to harvest.
- Apples – 56 days prior to harvest.
- Squash, pumpkins, marrow, melons – 14 days prior to harvest.
- Zucchini – 1 day prior to harvest.

The MRLs of 0.02 mg/kg, 0.1 mg/kg, 0.01 mg/kg and 0.1 mg/kg are therefore proposed to support GAP for grapes, apples cucurbits (inedible peel) and cucurbits (edible peel) consequently.

Dietary Risk Assessment

Potential Daily Exposure	0.25 mg/kg bw/day

The potential daily exposure via food (PDE_{food}) is used for dietary intake calculation where a value has been set.

The PDE_{food} is a value set by the Environmental Protection Authority (EPA), which represents the proportion of the acceptable daily exposure (ADE) to a substance via the food route as relevant to the New Zealand population. The methodology for calculation of these values is set out in the Hazardous Substances (classes 6, 8, and 9 controls) Regulations 2001 and can be found at www.legislation.govt.nz.

The chronic dietary exposure to proquinazid is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 1997 National Nutritional Survey for adults and the 1995 National Nutrition Survey of Australia, for children. The NEDI calculation is made in

accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

The NEDI for proquinazid is equivalent to less than 0.05% of the PDE_{food}. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological/Public Health Assessment

It has been determined that the use of proquinazid as a fungicide for grapes, apples and cucurbits, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Compound	Food	Maximum Residue Limit (mg/kg)
European Commission		
Proquinazid	Grapes	0.5
	Apples	0.02

Under Clause 6(3)(b) of the NZ (MRL) Food Standards 2011 imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications *Pesticide Residues in Food* or *Residues of Veterinary Drugs in Foods*.

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL represents a barrier to their trade.

2.4 PROPOSAL TO AMEND THE MRLS FOR AZINPHOS-METHYL

It is proposed that the MRL on kiwi fruit is deleted and that the food type is changed from fruit (except kiwifruit) to stonefruit and strawberries. The current entry for azinphos-methyl in Schedule One of the NZ (MRL) Food Standards 2011 is:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Azinphos-methyl	85-50-0	Azinphos-methyl	Fruits(except kiwifruit) Kiwifruit Potatoes	2 4 0.05(*)

NOTE: (*) indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

The final entry for azinphos-methyl in Schedule One of the NZ (MRL) Food Standards 2011 will therefore read:

Compound	CAS#	Residue definition	Food	Maximum Residue Limit (mg/kg)
Azinphos-methyl	85-50-0	Azinphos-methyl	Stonefruit Strawberries Potatoes	2 2 0.05(*)

NOTE: (*) indicates that the maximum residue limit has been set at or about the limit of analytical quantification.

Amendment Rationale

The proposed amendment is based on the EPA reassessment of azinphos-methyl and formulations containing azinphos-methyl. The EPA's decision includes the continue use of

the registered product; Cotnion 200 Insecticide (P7492) until the expiry of 31 December 2014 only on potato crops, summerfruit crops and strawberry runner plants. All other uses (including use on kiwifruit) are deleted.

International MRLs

Under clause 6(3)(b) of the MRL Standards imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications *Pesticide Residues in Food* or *Residues of Veterinary Drugs in Foods*. Codex has set a number of MRLs for the use of azinphos-methyl. It is anticipated that the Codex MRLs for azinphos-methyl will be sufficient to regulate imports of any commodity containing azinphos-methyl residues. However, if there is no relevant MRL set under the MRL Food Standards or set and published by Codex, all imported and domestically produced food must comply with the default MRL of 0.1mg/kg (refer MRL Standards clause 6).

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL amendments represents a barrier to their trade.

2.5 PROPOSAL TO DELETE THE MRLS FROM THE MRL STANDARDS 2011

It is proposed that the following entries are deleted from the Schedule 1 of the MRL Standard 2011.

Compound	CAS#	Residue to which the maximum residue limit applies	Food	MRL (mg/kg)
Baquiloprim	102280-35-3	Baquiloprim	Cattle fat Cattle kidney Cattle liver Cattle milk	0.15 0.01 0.3 0.03
Clopidol	2971-90-6	Clopidol	Edible offal of poultry Poultry meat	5 2
3, 5-Dinitro-o-toluamide	148-01-6	3,5-dinitro benzoic acid	Poultry meat	3
Dichlofluanid	1085-98-9	Dichlofluanid	Berries and other small fruits Vegetables	10 5
Bioallethrin	584-79-2	Bioallethrin, sum of isomers	Vegetables	2
Bioresmethrin	28434-01-7	Bioresmethrin	Vegetables	3
Fenbutatin oxide	13356-08-6	Fenbutatin oxide	Pome fruits Stone fruits	1 1

Amendment Rationale

There have been no products containing the above agricultural compounds and/or veterinary medicines registered in New Zealand under the ACVM Act 1997 over the last five years.

International MRLs

Under clause 6(3)(b) of the MRL Standards imported food may contain residues of agricultural compounds no greater than the MRLs specified for that food in the current editions or supplements of the FAO/WHO Codex Alimentarius Commission publications *Pesticide Residues in Food* or *Residues of Veterinary Drugs in Foods*. Codex has set a number of MRLs for the use of some of the above agricultural compounds and/or veterinary medicines. It is anticipated that the Codex MRLs for some of these agricultural compounds

and/or veterinary medicines will be sufficient to regulate imports of any commodity containing the above agricultural compounds and/or veterinary medicines residues. However, if there is no relevant MRL set under the MRL Food Standards or set and published by Codex, all imported and domestically produced food must comply with the default MRL of 0.1mg/kg (refer MRL Standards clause 6).

To meet New Zealand's obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures the proposed MRL will be notified to the World Trade Organization. Any country may choose to comment if they believe the proposed MRL deletion represents a barrier to their trade.

2.6 PROPOSAL TO EXTEND THE EXEMPTION OF DIDECYL DIMETHYL AMMONIUM CHLORIDE FROM AN MRL

It is proposed that the current MRL exemption of DDAC when applied as fungicide on pipfruits to be extended so that it covers use on fruits and vegetables.

It is proposed that Schedule Two of the MRL Standards be amended to include the following; and that this will be the resulting entry for DDAC in Schedule Two of the MRL Standards:

Compound	CAS#	Condition
Didecyl Dimethyl Ammonium Chloride	7173-51-5	When applied as a fungicide on fruits and vegetables

Amendment Rationale

The proposed MRL exemption represents a new use pattern for DDAC. The complexity of the compound i.e. it is a mixture of alkyl-quaternary ammonium salts with typical alkyl chain lengths of C8, C10 and C12, means it is not suitable to be managed against a concentration limit. Therefore it can be exempted from the requirement of an MRL.

Chemical Information

Common name of compound	Didecyl Dimethyl Ammonium Chloride
Use of compound	Sanitiser
Chemical Abstract Services (CAS) Registry number	7173-51-5
Type of compound	Quaternary ammonium
Administration method	Spray

Good Agricultural Practice (GAP)

DDAC is proposed for use as a fungicide treatment for pears, avocados, citrus, cucurbits, grapes, (seed) potatoes and tomatoes. Management of GAP through the establishment of MRLs has been deemed unsuitable given that there are too many other variables to allow a good judgment to be made as to whether an MRL breach would represent misuse, including its presence in exempt agricultural chemicals and in surface sanitizers.

Dietary Risk Assessment

No acceptable daily intake has been set for DDAC. However, it is used safely in many cleaning products for residential premise, public access premise and medical premise. Trace amounts of DDAC may be consumed with no incident through accidental contamination of food and water with surface cleaners. No dietary risk is expected through the use of DDAC on pears, avocados, citrus, cucurbits, grapes, (seed) potatoes and tomatoes.

Toxicological/Public Health Assessment

Apart from its corrosive property, DDAC does not trigger any of the chronic toxicity endpoints. Therefore, the exemption of DDAC from an MRL to the conditions specified

above is very unlikely to pose any health risks from consumption of the harvested commodity.