Ministry for Primary Industries
Manatū Ahu Matua

Proposals to Amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2013

MPI Discussion Paper No: 2013/36

Prepared by the Biosecurity, Food and Animal Welfare Directorate of the Ministry for Primary Industries

ISBN No: 978-0-478-42026-5 (online)
ISSN No: 2253-3907 (online)

August 2013

New Zealand Government

Growing and Protecting New Zealand

Disclaimer

Every effort has been made to ensure the information in this document is accurate.

MPI does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.
Requests for further copies should be directed to:

Publications Logistics Officer
Ministry for Primary Industries
PO Box 2526
WELLINGTON 6140

Email: brand@mpi.govt.nz
Telephone: 0800 00 83 33
Facsimile: 04-894 0300

This publication is also available on the Ministry for Primary Industries website at
http://www.mpi.govt.nz/news-resources/publications.aspx

Contents

Page

1 Submission

The Ministry for Primary Industries (MPI) invites public comment on this discussion document, which outlines **proposals to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards**.

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)
- Your address

Please submit your response by 5:00pm on 7 October 2013. Your comments should be sent to:

MRL Amendments
MPI Food Policy
PO Box 2835
Wellington

Email: FoodPolicy@MPI.govt.nz
Fax: (04) 894 2530

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. MPI 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.

2 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.

2.1 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 are available from the Ministry for Primary Industries (MPI) Foodsafety website at: http://www.foodsafety.govt.nz/elibrary/industry/register-list-mrl-agricultural-compounds.htm.

MPI 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
- 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 via food ($PDE_{(food)}$). Where there is no $PDE_{(food)}$, the estimated dietary intake is compared with the Acceptable Daily Intake (ADI). $PDE_{(food)}$ and ADI are described below.

A PDE (food) is a value determined by a toxicological evaluation by the Environmental Protection Authority (EPA) as part of its responsibility for managing public health under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act). A $PDE_{(food)}$ gives the potential daily exposure a person may be subject to from a substance, via food. MPI uses a $PDE_{(food)}$ where it is available, rather than the internationally-determined ADI, as required by 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 through a very similar scientific process.

An ADI 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 exposure”. ADIs are established by the WHO and Food and Agriculture Organization (FAO) of the United Nations joint expert committees, which are 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.

2.2 SUMMARY OF PROPOSED AMENDMENTS

The proposed MRLs have been thoroughly assessed in accordance with international methodologies, such as those utilised by the expert committees advising 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;
- residues information;
- dietary risk assessment;
- toxicological/public health assessment; and
- international MRLs.

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

Proposed MRLS

MPI proposes the following changes to the MRL Standards:

- 20 mg/kg for chlorantraniliprole when used as an insecticide on baby leafy vegetables;
- 0.05 mg/kg for isopyrazam when used as a fungicide on pumpkins and squash;
- 1.0 mg/kg in citrus and 0.02 in pome fruits for spirotetramat when used as in insecticide on citrus and pome fruits;
- 0.01(*) mg/kg on wheat grain, 0.01(*) mg/kg in milk, 0.01(*) mg/kg in muscle, 0.01(*) mg/kg in fat and 0.05 mg/kg in edible offal for sulfoxaflor when used as an insecticide on wheat;
- 0.01(*) mg/kg for tau-fluvalinate in milk, 0.01(*) mg/kg in mammalian meat, 0.01(*) mg/kg in edible offal and 0.02 mg/kg in mammalian fat when used as an insecticide on cereals, clover seed crops and oil seed rape;
- 5 mg/kg for thiomethoxam when used as an insecticide on leafy vegetables; and
- Exemption for formic acid from MRLs when used as an agricultural compound on bee colonies.

3 Proposals

3.1 PROPOSAL TO SET MRLS FOR CHLORANTRANILIPROLE

It is proposed that an MRL for chlorantraniliprole for baby leafy vegetables is added and the current entry for 'Leafy vegetables' is amended to read 'Leafy vegetables (Except baby leaf)'.

The current entry for chlorantraniliprole in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Chlorantraniliprole	500008-45-7	Chlorantraniliprole	Avocados	0.5
			Brassica vegetables	0.3
			Leafy vegetables	7
			Pome fruits	0.3
			Potatoes	0.01(*)

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

The revised entry for chlorantraniliprole in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Chlorantraniliprole	500008-45-7	Chlorantraniliprole	Avocados	0.5
			Brassica vegetables	0.3
			Baby leafy vegetables	20
			Leafy vegetables (Except baby leaf)	7
			Pome fruits	0.3
			Potatoes	0.01(*)

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

Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of chlorantraniliprole as an insecticide when applied as a seedling drench prior to transplanting in accordance with the application rates and withholding periods that are proposed as good agricultural practice in New Zealand. The current MRL for leafy vegetables is for the registered use of chlorantraniliprole as a foliar spray.

Chemical Information

Common name of compound	Chlorantraniliprole
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	500008-45-7
Type of compound	Diamide
Administration method	Spray

Good Agricultural Practice (GAP)

Chlorantraniliprole is proposed for use as an insecticide for control of white butterfly, diamond black moth, soya bean looper, aphids, greenhouse whitefly and onion thrip on baby leafy vegetable (seedling tray). Application is at a rate of 1.5g ai/1000 seedlings, with one application and a 18 day withholding period.

Residues Information

The residue data supports an MRL of 20 mg/kg for baby leafy vegetables when the last treatment is 18 days prior to harvest. Consequently, an MRL of 20 mg/kg in baby leafy vegetables is proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for the health based guidance value where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a PDE $_{(food)}$. The $PDE_{(food)}$ of 1.58 mg/kg bw/d was considered appropriate for use in the assessment of chlorantraniliprole.

The chronic dietary exposure to chlorantraniliprole 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 Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for chlorantraniliprole is less than 1% 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 chlorantraniliprole as an insecticide for leafy vegetables as a pre-transplant seedling tray drench according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Leafy vegetables (except lettuce, head and rucola)	15
	Lettuce, Head	3
	Rucola	T20
CODEX	Leafy vegetables	20
European Union	Leafy vegetables	20
USA	Vegetable, leafy, except brassica	13

T - Temporary

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.

3.2 PROPOSAL TO SET MRLS FOR ISOPYRAZAM

It is proposed that an MRL is set for isopyrazam for pumpkins and winter squash.

The current entry for isopyrazam in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Isopyrazam	881685-58-1	Isopyrazam, sum of isomers	Barley	0.5
			Wheat	0.2

The revised entry for isopyrazam in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Isopyrazam	881685-58-1	Isopyrazam, sum of isomers	Barley	0.5
			Pumpkins	0.05
			Wheat	0.2
			Winter Squash	0.05

Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of isopyrazam as a protectant fungicide to control powdery mildew on pumpkins and winter squash and in accordance with the application rates and withholding periods that are proposed as good agricultural practice in New Zealand.

Chemical Information

Common name of compound	Isopyrazam
Use of compound	Fungicide
Chemical Abstract Services (CAS) Registry number	881685-58-1
Type of compound	Pyrazole
Administration method	Spray

Good Agricultural Practice (GAP)

Isopyrazam is proposed for use as a protectant fungicide in pumpkins and winter squash. Application is at a rate of 600ml/ha at 14-21 day intervals, with no more than 2 applications per season and a 14 day withholding period.

Residues Information

The residue data for the crops supports an MRL of 0.05 mg/kg pumpkins and winter squash when the last treatment is 14 days prior to harvest. An MRL of 0.05 mg/kg in pumpkins and winter squash are proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for the health based guidance value where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.0385 mg/kg bw/d was considered appropriate for use in the assessment of isopyrazam.

The chronic dietary exposure to isopyrazam 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 Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for isopyrazam is less than 2% 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 isopyrazam as a protectant fungicide for pumpkins and winter squash according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Pumpkins	0.01(*)
	Winter Squash	0.01(*)

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.

3.3 PROPOSAL TO SET AN MRL FOR SPIROTETRAMAT

It is proposed that an MRL is set for spirotetramat for citrus and pome fruits.

The current entry for spirotetramat in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Spirotetramat	203313-25-1	*Sum of:* Spirotetramat and its enol metabolite *Expressed as*: Spirotetramat	Kiwifruit Potatoes Tomatoes Grapes	0.1 0.5 0.3 0.02(*)

The revised entry for spirotetramat in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Residue Limit (mg/kg)
Spirotetramat	203313-25-1	*Sum of:* Spirotetramat and its enol metabolite *Expressed as*: Spirotetramat	Citrus Grapes Kiwifruit Pome fruits Potatoes Tomatoes	1 0.02(*) 0.1 0.02 0.5 0.3

Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. They will manage the use of spirotetramat as an insecticide for the control of leafcurling midge in pears, and Kelly's citrus thrips and armoured scales in citrus in accordance with the application rates and withholding periods that are proposed as good agricultural practice in New Zealand.

Chemical Information

Common name of compound	Spirotetramat
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	203313-25-1
Type of compound	Tetramic acid
Administration method	Spray

Good Agricultural Practice (GAP)

Spirotetramat is proposed for use as an insecticide in pears and citrus at a rate of 96gai per hectare and 9.6gai per 100L respectively with withholding periods of 35 days for pome fruits and 21 days for citrus.

Residues Information

The residue data for pears (including apples) and citrus supports an MRL of 0.02 mg/kg for spirotetramat in pome fruits and 1 mg/kg in citrus when the above withholding periods are followed.

Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for the health based guidance value where a value has been set. An appropriate acceptable daily intake (ADI) is used in the

absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.004 mg/kg bw/d has been set by EPA and is considered appropriate for use in the assessment of spirotetramat.

The chronic dietary exposure to spirotetramat 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 Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for spirotetramat is equivalent to less than 50% 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 spirotetramat as an insecticide in pears and citrus according to GAP (specified above), is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Citrus	1
CODEX	Citrus	0.5
	Pome fruits	0.7
European Union	Citrus	1
	Pome fruits	1
Japan	Citrus	1
	Pear	0.7
USA	Citrus	0.6
	Pome fruits	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

3.4 PROPOSAL TO SET AN MRL FOR SULFOXAFLOR

It is proposed that an MRL is set for sulfoxaflor for wheat grain and for mammalian fat, kidney, liver, meat and milk as a result of residues in animal feed.

This will be the entry for sulfoxaflor in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Sulfoxaflor	946578-00-3	Sulfoxaflor	Edible offal (mammalian)	0.05
			Fat (Mammalian)	0.01(*)
			Milk	0.01(*)
			Meat (Mammalian)	0.01(*)
			Wheat grain	0.01(*)

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

Amendment Rationale

The proposed MRLs represent a use of a new active ingredient. They will manage the use of sulfoxaflor as an insecticide to control aphids in wheats in accordance with the application rates and withholding period that is proposed as good agricultural practice in New Zealand.

Chemical Information

Common name of compound	Sulfoxaflor
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	946578-00-3
Type of compound	Neonicotinoid
Administration method	Spray

Good Agricultural Practice (GAP)

Sulfoxaflor is proposed for use as an insecticide for wheats. Application rate is 12 - 24gai/ha and be applied up to BBCH 39 with a further application 14 days later if needed with a 28 days grazing restriction.

Residues Information

Residue data for wheat, data on animal metabolism and animal feeding studies support an MRL of 0.01(*) mg/kg for sulfoxaflor in wheat grain, 0.01(*) mg/kg in milk, 0.01(*) mg/kg in muscle, 0.01(*) mg/kg in fat and 0.05 mg/kg in edible offal at the proposed GAP. MRLs of 0.01(*) mg/kg in wheat grain, 0.01(*) mg/kg in milk, 0.01(*) mg/kg in muscle, 0.01(*) mg/kg in fat and 0.05 mg/kg in edible offal are therefore proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for the health based guidance value where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. The $PDE_{(food)}$ of 0.028 mg/kg bw/d has been set by EPA and is considered appropriate for use in the assessment of sulfoxaflor.

The chronic dietary exposure to sulfoxaflor 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 Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for sulfoxaflor is equivalent to less than 1% 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 sulfoxaflor as an insecticide for wheat according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
CODEX	Edible offal (mmammalian)	0.6
	Meat(Mammalian)	0.3
	Milk	0.2
	Wheat	0.2
USA	Mammalian fat	0.1
	Mammalian meat	0.15
	Milk	0.15
	Wheat grain	0.08

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.

3.5 PROPOSAL TO SET MRLS FOR TAU-FLUVALINATE

It is proposed that MRLs are set for tau-fluvalinate for cereal grain when used as an insecticide on cereals and in milk, meat, fat and edible offal when used as an insecticide on animal feed crops.

This will be the entry for tau-fluvalinate in Schedule One of the MRL Standards:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Tau-fluvalinate	102851-06-9	Tau-fluvalinate	Cereal grain	0.01(*)
			Edible offal (Mammalian)	0.01(*)
			Fat (Mammalian)	0.02
			Meat (Mammalian)	0.01(*)
			Milk	0.01(*)

Amendment Rationale

The proposed MRLs represent the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of tau-fluvalinate as an insecticide on cereals, clover seed crops and oil seed rape, to the application rates and withholding periods that are proposed as good agricultural practice in New Zealand.

Chemical Information

Common name of compound	Tau-fluvalinate
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	102851-06-9
Type of compound	Pyrethroid
Administration method	Spray

Good Agricultural Practice (GAP)

Tau-fluvalinate is used as an insecticide for cereals, clover seed crops and oil seed rape. Application rate is 18 - 36gai/ha and be applied as follows:

- Cereals - Apply after crop emergence and prior to tillering. If aphids continue to migrate into the crop, a second application should be made prior to the end of tillering. Do not apply more than two applications per season. 40 days restriction for cutting for hay or grazing.
- Clover seed crops - Apply in early December for clover case bearer moth, or when aphids appear. Withholding period of 56 days.
- Oil seed rape - Apply at first appearance of pest in the crop. May be applied during bee non-foraging periods. Withholding period of 63 days.

Residues Information

Residue data for cereals and data on animal metabolism and animal feeding studies support MRLs of 0.01(*) mg/kg in cereal grain, 0.01(*) in meat, milk and edible offal and 0.02 mg/kg in fat at the proposed withholding periods. MRLs of 0.01(*) mg/kg in cereal grain, 0.01(*) in meat, milk and edible offal and 0.02 mg/kg in fat are therefore proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for for the health based guidance value where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. MPI considered the ADI of 0.005 mg/kg bw/d was appropriate for use in the assessment of tau-fluvalinate.

The chronic dietary exposure to tau-fluvalinate 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 Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for tau-fluvalinate is equivalent to less than 20% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Toxicological/Public Health Assessment

MPI has determined that the use of tau-fluvalinate as an insecticide for cereals, clover seed crops and oil seed rape, according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
European Union	Mammalian fat	0.3
	Mammalian meat	0.05
	Mammalian edible offal	0.3
	Milk	0.05
	Barley	0.5
	Maize	0.1
	Oats	0.5
	Wheat	0.05

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.

3.6 PROPOSAL TO SET MRLS FOR THIAMETHOXAM

It is proposed that an MRL is set for thiamethoxam for leafy vegetables (seedling tray).

The current entry for thiamethoxam in Schedule One of the MRL Standards is:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Thiamethoxam	153719-23-4	Thiamethoxam	Kiwifruit	1
			Maize	0.02(*)
			Pome fruits	0.1
			Potatoes	0.02(*)
			Sweetcorn	0.02(*)

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

The revised entry for thiamethoxam in Schedule One of the MRL Standards will therefore read:

Compound Common Name	CAS#	Residue to which the maximum residue limit applies	Food	Maximum Permitted Residue Level (mg/kg)
Thiamethoxam	153719-23-4	Thiamethoxam	Kiwifruit	1
			Leafy vegetables	5
			Maize	0.02(*)
			Pome fruits	0.1
			Potatoes	0.02(*)
			Sweetcorn	0.02(*)

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

Amendment Rationale

The proposed MRL represents the expansion of use of a currently registered active ingredient. The proposed MRL will manage the use of thiamethoxam as an insecticide to control white butterfly, diamond black moth, soya bean looper, aphids, greenhouse whitefly and onion thrip on leafy vegetable (seedling tray) in accordance with the application rates and withholding periods that are proposed as good agricultural practice in New Zealand.

Chemical Information

Common name of compound	Thiamethoxam
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	153719-23-4
Type of compound	Neonicotinoid
Administration method	Spray

Good Agricultural Practice (GAP)

Thiamethoxam is proposed for use as an insecticide for control of white butterfly, diamond black moth, soya bean looper, aphids, greenhouse whitefly and onion thrip on leafy vegetable and brassica leafy vegetable (seedling tray). Application is at a rate of 3g ai/1000 seedlings, with one application and a 18 day withholding period.

Residues Information

The residue data supports an MRL of 5 mg/kg for leafy vegetables when the last treatment is 18 days prior to harvest. An MRL of 5 mg/kg in leafy vegetables is proposed to support GAP.

Dietary Risk Assessment

The potential daily exposure via food ($PDE_{(food)}$) is used for for the health based guidance value where a value has been set. An appropriate acceptable daily intake (ADI) is used in the absence of a $PDE_{(food)}$. MPI considered the ADI of 0.08 mg/kg bw/d was appropriate for use in the assessment of thiamethoxam.

The chronic dietary exposure to thiamethoxam 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 Nutrition Survey for adults (New Zealand) and the 1995 National Nutrition Survey (Australia), for children. The NEDI calculation is made in accordance with *Guidelines for predicting dietary intake of pesticide residues (revised)* [World Health Organization, 1997].

Based on the proposed MRLs, the NEDI for thiamethoxam is less than < 5% 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 thiamethoxam as an insecticide for leafy vegetables according to the GAP specified above, is very unlikely to pose any health risks from consumption of treated produce.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
Australia	Leafy vegetables	2
CODEX	Leafy vegetables	3
European Union	Leafy vegetables	5
USA	Vegetable, leafy, except brassica	4

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.

3.7 PROPOSAL TO EXEMPT FORMIC ACID FROM AN MRL

It is proposed that an MRL exemption is set for formic acid when used as an agricultural compound in bee colonies.

It is proposed that Schedule Two of the MRL Standards be amended by adding the following:

Substance	CAS#	Condition
Formic acid	64-18-6	Used as a pesticide in bee colonies

Amendment Rationale

The proposed MRL exemption represents a new use pattern in New Zealand for formic acid. Formic acid is a common substance in food, with general approvals for use as a flavouring agent in beverages, ice cream, sweets, baked goods and processed cheeses. Available studies indicated that there is a large variation in natural levels of formic acid. In addition, the treatment appears to have no correlation with residues remaining in honey. Formic acid would continuously decompose during storage thus residues would not be reliably representative of treatment after a certain period. Therefore, establishing a suitable concentration for a residue limit is difficult.

Chemical Information

Common name of compound	Formic acid
Use of compound	Insecticide
Chemical Abstract Services (CAS) Registry number	64-18-6
Type of compound	Carboxylic acid
Administration method	Strips

Good Agricultural Practice

Formic acid is proposed for use as an insecticide to control varroa mites in honeybee colonies with a no harvest period of 2 weeks from end of treatment.

Residues Information

Formic acid is a common substance in food, with general approvals for use as a flavouring agent in beverages, ice cream, sweets, baked goods and processed cheeses. Available studies indicated that there is a large variation in natural levels of formic acid. In addition, the treatment appears to have no correlation with residues remaining in honey. Formic acid would continuously decompose during storage thus residues would not be reliably representative of treatment after a certain period. Therefore, it is not appropriate to be regulated against an MRL.

Dietary Risk Assessment

Formic acid is a common substance in food. It would continuously decompose during storage. It is an irritant to the ocular and respiratory organs. It has a relatively low taste threshold with an acrid and unpleasant taste thus excessive levels being present in honey would likely be self-limiting in regards to health concerns due to the repellence from the taste. Therefore, the exemption of formic acid from an MRL to the conditions specified above is very unlikely to pose any health risks from consumption of the harvested commodity.

Toxicological/Public Health Assessment

Formic acid is well tolerated orally. It is only an irritant to the ocular and respiratory organs. It does not trigger any of the chronic toxicity endpoints. Therefore, the exemption of formic

acid from an MRL to the conditions specified above is very unlikely to pose any health risks from consumption of the harvested commodity.

Other International MRLs

Country	Food	Maximum Residue Limit (mg/kg)
USA	Honey and Honeycomb	Exempt when used to control tracheal mites and suppress varroa mites in bee colonies, and applied in accordance with label use directions

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.