



Consultation on proposals to amend the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006: October - December 2006

Introduction

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 2006.

Maximum residue limits (MRLs) indicate the maximum permissible levels at which residues of agricultural compounds are allowed in food for sale in New Zealand. The New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards are issued by the Minister for Food Safety under section 11C of the Food Act 1981.

Routine amendments to these Food Standards are made a number of times a year to reflect changes in the uses of agricultural compounds in the production of food.

Proposed changes

NZFSA proposes to add the following seven MRLs to Schedule One of the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006 (Technical information on each proposed MRL is included in Appendix One):

- 3.0mg/kg for closantel in cattle fat, 3.0mg/kg for closantel in cattle kidney, 1.0mg/kg for closantel in cattle liver and 1.0mg/kg for closantel in cattle muscle;
- 0.15mg/kg for doramectin in milk;
- 0.02mg/kg for fenpropidin in barley and 0.02mg/kg for fenpropidin in wheat;
- 0.01mg/kg for mesotrione in maize;
- 0.01mg/kg for pinoxaden in cereal grains;
- 0.01mg/kg for ractopamine in pig fat, 0.09mg/kg for ractopamine in pig kidney, 0.04mg/kg for ractopamine in pig liver and 0.01mg/kg for ractopamine in pig muscle; and
- 0.3mg/kg for trifloxystrobin on citrus (except Clementine/Satsuma mandarins), 0.02mg/kg for trifloxystrobin in grapes, 0.02mg/kg for trifloxystrobin in mandarins (Clementine/Satsuma) and 0.02mg/kg for trifloxystrobin in stone fruits (except cherries).

The submission process

NZFSA seeks submissions from all interested parties on any of the proposals presented in this document. Please provide technical support for your argument and include the following information in your submission:

- your name (and title, if applicable)
- your organisation's name (if applicable)
- your address and contact details.

Please note that your submission is public information and subject to the Official Information Act 1982. Therefore, if you consider that any or all information in your submission should be treated as confidential or is commercially sensitive, please state this clearly when making your submission.

Deadline for receipt of submissions

Please note the deadline for receipt of submissions is **Wednesday 6 December 2006**.

For further information

Queries and submissions should be directed to:

| | |
|-----------------------------------|-----------------------------|
| MRL Amendments | Email: policy@nzfsa.govt.nz |
| Policy Group | Phone: 04 463 3439 |
| New Zealand Food Safety Authority | Facsimile: 04 463 2583 |

PO Box 2835
Wellington

The next step

Following the closing date for submissions (6 December 2006), all submissions will be considered and analysed before a recommendation is made to the Minister for Food Safety, the Hon Annette King, who makes the final decision on issuing any amendments to the Food 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*.

Index for Appendix One: Technical information sheets for proposed MRLs

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Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

1. Proposal to set MRLs for Closantel

It is proposed that MRLs are set for closantel when used as an anthelmintic for cattle.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|-----------|------------|--------------------|---------------|-------------------------------|
| Closantel | 57808-65-8 | Closantel | Cattle fat | 3 |
| | | | Cattle kidney | 3 |
| | | | Cattle liver | 1 |
| | | | Cattle muscle | 1 |

The resulting entry for closantel in Schedule One of the NZ (MRL) Food Standards 2006 will therefore read:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|-----------|------------|--------------------|-----------------------|-------------------------------|
| Closantel | 57808-65-8 | Closantel | Cattle fat | 3 |
| | | | Cattle kidney | 3 |
| | | | Cattle liver | 1 |
| | | | Cattle muscle | 1 |
| | | | Edible offal of sheep | 5 |
| | | | Sheep meat | 2 |

Chemical Information

| | |
|---|------------------------|
| Common name of compound | Closantel |
| Use of compound | Anthelmintic |
| Chemical Abstract Services (CAS) Registry number | 57808-65-8 |
| Type of compound | Salicylanilide |
| Administration method | Subcutaneous Injection |

Residues Information

The proposed closantel MRLs have been determined in order to manage residues resulting from good agricultural practice (GAP) as determined by Codex Alimentarius.

Dietary Risk Assessment

| | |
|--------------------------------------|------------------|
| Acceptable Daily Intake (ADI) | 0.03mg/kg bw/day |
|--------------------------------------|------------------|

For dietary intake calculations the potential daily exposure via food ($PDE_{(food)}$) is used if a value has been set by New Zealand's Environmental Risk Management Authority. In the absence of a $PDE_{(food)}$ an appropriate acceptable daily intake (ADI) is used instead. In the case of closantel, the ADI has been set by the Joint Expert Committee on Food Additives (JECFA).

The chronic dietary exposure to closantel 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 for closantel is equivalent to 10% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Risk Assessment

It has been determined that the use of closantel as an injectable anthelmintic for cattle is very unlikely to pose any toxicological health risks from consumption of the processed cattle fat, kidney, liver or muscle.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, thus for imported food containing this agricultural compound the following Codex Alimentarius MRLs are applicable:

| Compound | Food | Maximum Residue Limit (mg/kg) |
|-----------|---------------|-------------------------------|
| Closantel | Cattle fat | 3 |
| | Cattle kidney | 3 |
| | Cattle liver | 1 |
| | Cattle muscle | 1 |

Other International MRLs

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



Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

2. Proposal to set a MRL for Doramectin

It is proposed that a MRL is set for doramectin when used as an anthelmintic for cattle.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|------------|-------------|--------------------|------|-------------------------------|
| Doramectin | 117704-25-3 | Doramectin | Milk | 0.015 |

The resulting entry for doramectin in Schedule One of the NZ (MRL) Food Standards 2006 will therefore read:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|------------|-------------|--------------------|---------------|-------------------------------|
| Doramectin | 117704-25-3 | Doramectin | Cattle fat | 0.15 |
| | | | Cattle kidney | 0.03 |
| | | | Cattle liver | 0.1 |
| | | | Cattle meat | 0.01 |
| | | | Milk | 0.015 |
| | | | Pig fat | 0.15 |
| | | | Pig kidney | 0.03 |
| | | | Pig liver | 0.1 |
| | | | Pig meat | 0.01 |
| | | | Sheep fat | 0.15 |
| | | | Sheep kidney | 0.03 |
| | | | Sheep liver | 0.1 |
| | | | Sheep meat | 0.01 |

Chemical Information

| | |
|---|-------------------------|
| Common name of compound | Doramectin |
| Use of compound | Veterinary anthelmintic |
| Chemical Abstract Services (CAS) Registry number | 117704-25-3 |
| Type of compound | Avermectin |
| Administration method | Topical |

Residues Information

The proposed doramectin MRL has been determined in order to manage residue resulting from good agricultural practice (GAP) as determined by Codex Alimentarius

Dietary Risk Assessment

| | |
|--------------------------------------|-------------------|
| Acceptable Daily Intake (ADI) | 0.001mg/kg bw/day |
|--------------------------------------|-------------------|

For dietary intake calculations the potential daily exposure via food ($PDE_{(food)}$) is used if a value has been set by New Zealand's Environmental Risk Management Authority. In the absence of a $PDE_{(food)}$, an appropriate acceptable daily intake (ADI) is used instead. In the case of doramectin, the ADI has been set by the Joint Expert Committee on Food Additives (JECFA).

The chronic dietary exposure to doramectin is estimated by the National Estimated Dietary Intake (NEDI) calculation encompassing all registered uses of the chemical and food consumption data based upon the 2006 World Health Organisation's Global Environmental Monitoring System (Cluster Diet: M) and the 1995 National Nutrition Survey of Australia, for children.

The NEDI for doramectin is equivalent to approximately 60% of the ADI. It is therefore concluded that the chronic dietary exposure is tolerable and the risk posed is acceptable.

Public Health Risk Assessment

It has been determined that the use of doramectin as a topical anthelmintic on cattle is very unlikely to pose any toxicological health risks from consumption of milk.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, thus for imported food containing this agricultural compound the following Codex Alimentarius MRLs are applicable:

| Compound | Food | Maximum Residue Limit (mg/kg) |
|------------|------|-------------------------------|
| Doramectin | Milk | 0.015 |

Other International MRLs

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



Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

3. Proposal to set MRLs for Fenpropidin

It is proposed that MRLs are set for fenpropidin when used as a fungicide for barley and wheat.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for fenpropidin in Schedule One of the NZ (MRL) Food Standards 2006:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|-------------|------------|--------------------|-----------------|-------------------------------|
| Fenpropidin | 67306-00-7 | Fenpropidin | Barley Wheat | 0.02(*) 0.02(*) |

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

Chemical Information

| | |
|--|--------------|
| Common name of compound | Fenpropidin |
| Use of compound | Fungicide |
| Chemical Abstract Services (CAS) Registry number | 67306-00-7 |
| Type of compound | Piperidine |
| Administration method | Foliar spray |

Good Agricultural Practice (GAP)

Fenpropidin is proposed for use as a fungicide for wheat and barley. Application may be throughout plant growth stages 29-33 and 39-49, at 750gai/ha with a withholding period of 70 days.

Residues Information

Residue data from trials reflecting the above GAP indicate that no measurable residues should be present in grain at harvest 70 days after the last treatment. An MRL of 0.02mg/kg* is therefore proposed to support GAP.

Dietary Risk Assessment

| | |
|-------------------------------|-------------------|
| ERMA NZ PDE _(food) | 0.016mg/kg bw/day |
|-------------------------------|-------------------|

The potential daily exposure via food (PDE_(food)) is used for dietary intake calculations. The PDE_(food) is a value set by the Environmental Risk Management Authority, and 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 fenpropidin 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 Organisation, 1997].

The NEDI for fenpropidin is equivalent to 4% of the ADI. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of fenpropidin as a fungicide for use on barley and wheat, according to the good agricultural practice specified above, is very unlikely to pose any toxicological health risks from consumption of the harvested commodity.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

Other International MRLs

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



Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

4. Proposal to set a MRL for Mesotrione

It is proposed that a MRL is set for mesotrione when used as a herbicide for maize.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for mesotrione in Schedule One of the NZ (MRL) Food Standards 2006:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|------------|-------------|--------------------|-------|-------------------------------|
| Mesotrione | 104206-82-8 | Mesotrione | Maize | 0.01* |

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

Chemical Information

| | |
|--|---|
| Common name of compound | Mesotrione |
| Use of compound | Herbicide |
| Chemical Abstract Services (CAS) Registry number | 104206-82-8 |
| Type of compound | Benzoylcyclohexanedione |
| Administration method | Boom spraying |

Good Agricultural Practice (GAP)

Mesotrione is proposed for use as a broadleaf herbicide for maize. Application may be as a pre-emergent treatment at 168-216 gai/ha, or a post-emergent treatment before crops reach the second leaf stage or 75cm in height at 72-96 gai/ha.

Residues Information

Residue data from trials reflecting the above GAP indicate that measurable residues should not occur in grain from maize treated according to the above GAP. An MRL of 0.01 mg/kg* is therefore proposed to support GAP.

Dietary Risk Assessment

| | |
|---------------------------------|-------------------|
| Acceptable Daily Intake (ADI) | 0.01mg/kg bw/day |
| Acceptable Daily Exposure (ADE) | 0.01mg/kg bw/day |
| ERMA NZ PDE _(food) | 0.006mg/kg bw/day |

The potential daily exposure via food ($PDE_{(food)}$) is used for dietary intake calculations. The $PDE_{(food)}$ is a value set by the Environmental Risk Management Authority, and 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 mesotrione 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 Organisation, 1997].

The NEDI for mesotrione is equivalent to 4% of the $PDE_{(food)}$. It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of mesotrione as a herbicide for use on maize, according to the GAP specified above, is very unlikely to pose any toxicological health risks from consumption of the harvested commodity.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

Other International MRLs

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



Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

5. Proposal to set a MRL for Pinoxaden

It is proposed that a MRL is set for Pinoxaden when used as a herbicide for cereal grains.

It is proposed that Table One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for pinoxaden in Schedule One of the NZ (MRL) Food Standards 2006:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|-----------|-------------|--|---------------|-------------------------------|
| Pinoxaden | 243973-20-8 | Sum of: Pinoxaden and its M2 metabolite: (8-(2,6-diethyl-4-methyl-phenyl)-tetrahydro-9H-pyrazolo[1,2-d][1,4,5]oxadiazepine-7,9-dione <i>expressed as:</i> Pinoxaden | Cereal grains | 0.01(*) |

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

Chemical Information

| | |
|---|---------------------------|
| Common name of compound | Pinoxaden |
| Use of compound | Herbicide |
| Chemical Abstract Services (CAS) Registry number | 243973-20-8 |
| Type of compound | Phenylpyrazolin herbicide |
| Administration method | Boom spray |

Good Agricultural Practice (GAP)

Pinoxaden is proposed for use as a herbicide for wheat and barley. GAP is for use as a boom spray (25-30 g ai/ha) when grass weeds are between the third leaf stage and the first node formation, with a withholding period of 70 days.

Residues Information

Residue data from trials reflecting the above GAP on wheat and barley indicate that measurable residues should not occur in grain at harvest, 70 days after treatment. The residue assessment has also indicated that this conclusion can be extended to include all cereals. An MRL of 0.01mg/kg* for cereal grains is therefore proposed to support GAP.

Dietary Risk Assessment

| | |
|--|-------------------|
| ERMA NZ Acceptable Daily Exposure (ADE) | 0.1 mg/kg bw/day |
| ERMA NZ PDE_(food) | 0.06 mg/kg bw/day |

The potential daily exposure via food (PDE_(food)) is used for dietary intake calculations. The PDE_(food) is a value set by the Environmental Risk Management Authority, and 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 Pinoxaden 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 Organisation, 1997].

The NEDI for Pinoxaden is equivalent to 0.02% of the PDE_(food). It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of Pinoxaden as a herbicide for use on wheat and barley, according to the GAP specified above, is very unlikely to pose any toxicological health risks from consumption of the harvested commodity.

Consideration of International MRLs**Codex MRLs**

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

Other International MRLs

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



Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

6. Proposal to set MRLs for Ractopamine

It is proposed that MRLs are set for ractopamine when used as a growth stimulant for pigs.

It is proposed that Schedule One of the NZ (MRL) Food Standards 2006 be amended to include the following, this will be the resulting entry for ractopamine in Schedule One of the NZ (MRL) Food Standards 2006:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|-------------|------------|--------------------|--|-------------------------------|
| Ractopamine | 97825-25-7 | Ractopamine | Pig fat Pig kidney Pig liver Pig muscle | 0.01 0.09 0.04 0.01 |

Chemical Information

| | |
|---|-------------------------|
| Common name of compound | Ractopamine |
| Use of compound | Growth stimulant |
| Chemical Abstract Services (CAS) Registry number | 97825-25-7 |
| Type of compound | Adrenergic beta-agonist |
| Administration method | Orally in animal feed |

Residues Information

Residue data for pigs supports MRLs of 0.01mg/kg for fat and muscle, 0.04mg/kg for liver and 0.09mg/kg for kidney at 12 hours after the last treatment.

Dietary Risk Assessment

| | |
|--|-------------------|
| Acceptable Daily Intake (ADI) | 0.001mg/kg bw/day |
| Acceptable Daily Exposure (ADE) | 0.001mg/kg bw/day |
| ERMA NZ PDE_(food) | 0.001mg/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 Risk Management Authority, and 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 ractopamine 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 for ractopamine is equivalent to 2% of the ADI/PDE_(food). It is therefore concluded that the chronic dietary exposure is small and the risk is acceptable.

Public Health Assessment

It has been determined that the use of ractopamine as a growth stimulant for use on pigs, according to GAP, is very unlikely to pose any toxicological health risks from consumption of the processed pig fat, liver, kidney and muscle.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, currently no Codex Alimentarius MRLs have been determined for this agricultural compound.

Other International MRLs

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



Proposed amendment to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2006

7. Proposal to set MRLs for Trifloxystrobin

It is proposed that MRLs are set for trifloxystrobin when used as a fungicide for citrus fruits, grapes and stone fruits.

It is proposed that Table One of the NZ (MRL) Food Standards 2006 be amended to include:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|-----------------|-------------|--|--|-------------------------------|
| Trifloxystrobin | 141517-21-7 | <i>Sum of:</i> trifloxystrobin and its free acid metabolite. <i>expressed as:</i> trifloxystrobin equivalents | Citrus (except Clementine and Satsuma mandarins) | 0.3 |
| | | | Grapes | 0.02(*) |
| | | | Mandarins (Clementine/ Satsuma) | 0.02(*) |
| | | | Stone fruits (except cherries) | 0.02(*) |

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

The resulting entry for trifloxystrobin in Schedule One of the NZ (MRL) Food Standards 2006 will therefore read:

| Compound | CAS# | Residue definition | Food | Maximum Residue Limit (mg/kg) |
|-----------------|-------------|--|--|-------------------------------|
| Trifloxystrobin | 141517-21-7 | <i>Sum of:</i> trifloxystrobin and its free acid metabolite. <i>expressed as:</i> trifloxystrobin equivalents | Cereal grains | 0.05(*) |
| | | | Citrus (except Clementine and Satsuma mandarins) | 0.3 |
| | | | Cucurbits (inedible peel) | 0.02(*) |
| | | | Grapes | 0.02(*) |
| | | | Kiwifruit | 0.02(*) |
| | | | Mandarins (Clementine/ Satsuma) | 0.02(*) |

| | | | | |
|--|--|--|--------------------------------------|---------|
| | | | Pome fruits | 0.02(*) |
| | | | Stone fruits (except cherries) | 0.02(*) |

Chemical Information

| | |
|---|------------------------|
| Common name of compound | Trifloxystrobin |
| Use of compound | Fungicide |
| Chemical Abstract Services (CAS) Registry number | 141517-21-7 |
| Type of compound | Strobilurin derivative |
| Administration method | Foliar spray |

Good Agricultural Practice (GAP)

Citrus fruits: Trifloxystrobin is proposed for use as a fungicide on citrus. GAP is for foliar spray application over the flowering/fruit set period at a rate of 5gai/100 litres of water, with a repeat application up to one month after fruit set. Withholding periods of 120 days for mandarins (Clementine/Satsuma), and 28 days for other citrus fruit are consistent with this GAP.

Grapes: Trifloxystrobin is proposed for use as a fungicide on grapes. GAP is for foliar spray applications over flowering and up to bunch-closure at 14 day intervals at a rate of 6.25 gai/100 litres. A withholding period of 56 days is consistent with this GAP.

Stone fruits (except cherries): Trifloxystrobin is proposed for use as a fungicide on stone fruits (except cherries). GAP is for foliar spray applications (6.25 gai/100 litres) over flowering, up to petal-fall.

Residues Information

Citrus fruits: Residue data from trials reflecting the above GAP on Clementine and Satsuma mandarins indicate that measurable residues should not occur in fruit at harvest, 120 days after treatment. This supports an MRL at the limit of analytical quantification of 0.02 mg/kg at 120 days after the last treatment. Residue data from trials reflecting the above GAP on other citrus fruits indicate residues of trifloxystrobin and its free acid metabolite should not exceed 0.22 mg/kg at harvest, 28 days after treatment. MRLs of 0.02mg/kg* for mandarins (Clementine and Satsuma), and 0.3 mg/kg for other citrus are therefore proposed to support the above GAP.

Grapes: Residue data from trials reflecting the above GAP on grapes indicate that measurable residues should not occur in fruit at harvest, 56 days after treatment. A MRL of 0.02mg/kg is therefore proposed to support the above GAP.

Stone fruits (except cherries): Residue data from trials reflecting the above GAP on stone fruits (except cherries) indicate that measurable residues should not occur in fruit at harvest, following treatments up to petal-fall. A MRL of 0.02mg/kg is therefore proposed for stone fruit (except cherries) to support the above GAP.

Dietary Risk Assessment

| | |
|--------------------------------------|------------------|
| Acceptable Daily Intake (ADI) | 0.04mg/kg bw/day |
|--------------------------------------|------------------|

For dietary intake calculations the potential daily exposure via food ($PDE_{(food)}$) is used if a value has been set by New Zealand's Environmental Risk Management Authority. In the absence of a $PDE_{(food)}$, an appropriate acceptable daily intake (ADI) is used instead. In the case of trifloxystrobin, the ADI has been set by the Joint Expert Committee on Food Additives (JECFA).

The chronic dietary exposure to trifloxystrobin 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 Organisation, 1997].

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

Public Health Assessment

It has been determined that the use of trifloxystrobin as a fungicide for use on citrus fruits and stone fruits (except cherries), according to the good agricultural practice specified above in addition to currently registered uses of trifloxystrobin in New Zealand, is very unlikely to pose any toxicological health risks from consumption of the harvested commodity.

Consideration of International MRLs

Codex MRLs

As specified in the NZ (MRL) Food Standards 2006 imported foods may contain agricultural compounds no greater than the level specified by Codex Alimentarius, thus for imported food containing this agricultural compound the following Codex Alimentarius MRLs are applicable:

| Compound | Food | Maximum Residue Limit (mg/kg) |
|-----------------|-------------|--------------------------------------|
| Trifloxystrobin | Pome fruits | 0.7 |

Other International MRLs

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