Hydrogen Cyanamide

New Zealand Environmental and Human Health Risk Assessment Report to Support Reassessment.

Report Submitted To:

New Zealand Kiwifruit Growers Incorporated
Mount Maunganui South, New Zealand

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1 Introduction

Hydrogen cyanamide is an important chemical for use in kiwifruit in New Zealand. The New Zealand Environment Protection Agency (EPA) concluded in September 2019 that grounds exist for the reassessment of soluble concentrate containing 520 to 540 g/L hydrogen cyanamide. Specifically, it was considered that the EFSA document “Conclusion on the peer review of the pesticide risk assessment of the active substance cyanamide” is significant new information relating to the effects of the substance under section 62(2)(a) of the HSNO Act.

In the EFSA Peer Review document provided by the applicant, the critical areas of concerns are the operator and bystander exposure estimates which exceed the Acceptable Operator Exposure Level (AOEL), as well as the potential for groundwater exposure. A high risk to birds was also identified but the risk assessment could not be finalised on the basis of the available data.

The European Commission decision was published two years after the previous ERMA reassessment decision for hydrogen cyanamide. It was therefore not possible for these documents to be taken into account in the decision process on the reassessment and the time, and hence the reason for the EFSA report to now be considered as new information.

The EPA staff report for establishing grounds for reassessment, did not take into account a more recent international assessment from what would presumably be a trusted regulator, the United States Environmental Protection Agency (US EPA). Their assessment was finalised more recently (2016) than the EFSA conclusion. As is often the case with reports from different international regulators, the end-points used in the assessment process are significantly different despite essentially the same data set being assessed, and this leads to different conclusions. The EPA does not have guidance on a preference for, or ranking of reliance, of different international regulators. It is therefore assumed that if the EFSA conclusion is to be considered new information sufficient to provide grounds for reassessment, then the findings of the US EPA assessment should equally be considered. These are both described and applied in the following risk assessment report.

In undertaking the following risk assessment, end-points for hydrogen cyanamide have been identified from the available data set, namely, results available in the EFSA (2010) and US EPA (2016) reports and their supporting documents. In the initial assessment, outcomes have modelled to the extent possible following the New Zealand EPA methodologies as described in their “Risk Assessment Methodology for Hazardous Substances” document (January 2020). Where this methodology is not followed, rationale is provided.

This risk assessment has been undertaken for birds (environment) and occupational risk (human health) given the issues identified in the grounds for re-assessment. In addition, an aquatic risk assessment has been undertaken to identify updated controls based on current EPA methodology. EFSA (2010) concluded the risk to bees, non-target arthropods, earthworms, non-target soil macro- and micro-organisms and non-target terrestrial plants was low. Therefore, a risk assessment for these organisms has not been performed. Where a risk is identified, and controls based on the EPA methodology are not sufficient to mitigate risk to an acceptable level, further refinements have been undertaken. These may include scientific argument, or additional modelling using internationally accepted approaches outside the EPA’s current suite of methodologies.

Use Pattern

Table 1: Kiwifruit for Hydrogen Cyanamide – based on Hi-Cane 520 g/L Hydrogen Cyanamide formulation (soluble concentrate)

Crop and/or situation (a)	Use pattern (b)	Pests or group of pests controlled I	Mixture		Application				Application rate per treatment	
			Type (d-f)	Conc of a.i. (g)	Method and kind (h-i)	Growth stage & season (j)	Number Min max (k)	Interval between applications – days (minimum)	water L/ha min max	kg a.i./ha max
Kiwifruit	Field	Plant growth regulator	Soluble concentrate	520 g/L	High volume ground spraying	Dormant vines (prior to bud break)	1	-	**Mature vines** 500-700 **DO NOT exceed** 800	(Apply 4-6 L HiCane/100 L water) **10.4-15.6** (500 L spray/ha) **14.6-21.8** (700 L spray/ha) **16.6-25.0** (800 L spray/ha)

a Where relevant, the use situation should be described (e.g. fumigation of soil)
b Outdoor or field use (F), glasshouse application (G) or indoor application (I).
c e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds
d e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
e CropLife international, 2008. Technical Monograph no 2, 6th edition. Catalogue of pesticide formulation types and international coding system
f All abbreviations used must be explained
g g/kg or g/l or others
h Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, aerial, etc ,
i Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated. If spraying include droplet size spectrum
j growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell (ISBN 3-8263-3152-4), including where relevant, information on season at time of application
k Indicate the minimum and maximum number of application possible under practical conditions of use
l Remarks may include: Extent of use/economic importance/restrictions

2 Identity of the active ingredients, physico-chemical properties, use pattern and mode of action

Identity

Active constituent	Cyanamide	Reference/comments
Chemical name (CAS)	Cyanamide	
CAS No.	420-04-2	
Molecular formula	CH_2N_2	
Molecular mass	42.05	
Structural formula	$N{\equiv}C{-}NH_2$	

Physico-chemical properties

		Reference
Melting point	46.1°C (99.7 %)	EFSA, 2010
Boiling point	Decomposition before boiling	EFSA, 2010
Appearance	Colourless solid (> 96%)	EFSA, 2010
Vapour pressure	0.51 Pa at 20 °C (100.3 %) 1.0 Pa at 25 °C (100.3 %)	EFSA, 2010
Henry's Law Constant	2.68×10^{-5} Pa m^3/mol (20°C)	EFSA, 2010
Water solubility	> 800 g/L at 20 °C (pH 3.8) (> 96 %) > 560 g/L at 20 °C (pH 7; from preliminary test) > 530 g/L at 20 °C (pH 9 – 11; from preliminary test)	EFSA, 2010
Partition co-efficient	log $P_{O/W}$ = - 0.72 at 20°C (pH 6.8) (100 %) No influence of the pH-value.	EFSA, 2010

3 Environmental Fate

Residues relevant to the environment

No metabolites in soil were identified as requiring further consideration.

Table 2: Identified environmental metabolites for cyanamide.

Metabolite code	Environmental compartment	Maximum formation
Urea	Water (photolysis)	12.2% of initial measured dose after 30 days.

Degradation and fate of cyanamide in the soil environment

The following table summarises the environmental fate end-points for cyanamide.

Table 3: Degradation and fate in soil environments

<table>
<tr><th>Test type</th><th>Value</th><th>Reference</th></tr>
<tr><td>Aerobic soil degradation</td><td>
<table>
<tr><th>Soil type</th><th>% OC / pH</th><th>DT_{50} [d]</th><th>DT_{90} [d]</th><th>Kinetic model</th></tr>
<tr><td>Sandy loam</td><td>0.93 / 6.8</td><td>0.58</td><td>1.94</td><td>SFO</td></tr>
<tr><td>Loamy sand</td><td>2.19 / 5.6</td><td>0.90</td><td>2.99</td><td>SFO</td></tr>
<tr><td>Loamy sand</td><td>1.10 / 7.2</td><td>1.61</td><td>5.35</td><td>SFO</td></tr>
<tr><td>Sand</td><td>0.48 / 6.5</td><td>5.33</td><td>17.7</td><td>SFO</td></tr>
</table>
94.6% mineralization after 14 days (study end), ^{14}C-hydrogen cyanamide (n=1)
5.64% non-extractable residues after 14 days (study end), ^{14}C-hydrogen cyanamide (n = 1).
No major metabolites</td><td>EFSA, 2010</td></tr>
<tr><td></td><td>
<table>
<tr><th>Soil</th><th>Classification</th><th>WHC (%)</th><th>T (°C)</th><th>DT_{50}</th></tr>
<tr><td>RefeSol 02-A</td><td>Silt loam</td><td>21
10.4</td><td>12
12</td><td>1.15
1.06</td></tr>
<tr><td>RefeSol 01-A</td><td>Loamy sand</td><td>10
5</td><td>20
20</td><td>0.95
0.82</td></tr>
<tr><td>RefeSol 06-A</td><td>Silty clay</td><td>16
32</td><td>20
20</td><td>0.55
0.42</td></tr>
<tr><td>Dugliolo di Budrio</td><td>Silt</td><td>9.1
18</td><td>20
20</td><td>0.79
1.21</td></tr>
</table></td><td>Weinfurtner, 2019</td></tr>
<tr><td></td><td>
<table>
<tr><th>Soil</th><th>Classification</th><th>WHC (%)</th><th>T (°C)</th><th>DT_{50}</th></tr>
<tr><td>RefeSol 01-A</td><td>Loamy sand</td><td>10
5</td><td>12
12</td><td>2.2
1.3</td></tr>
</table></td><td>Güthner, 2018</td></tr>
<tr><td></td><td>Final value for environmental exposure modelling – 80th percentile 1.4 days</td><td></td></tr>
<tr><td>Anaerobic soil degradation</td><td>53.1% mineralisation after 60 d.
6.93% non-extractable residues after 60 days.
No major metabolites</td><td>EFSA, 2010</td></tr>
</table>

<table>
<tr><th>Test type</th><th>Value</th><th>Reference</th></tr>
<tr><td>Soil adsorption/ desorption</td><td>
<table>
<tr><th>Soil</th><th>pH</th><th>OC [%]</th><th>K_d</th><th>K_{OC}</th></tr>
<tr><td>Sand (8.97 mg/L)</td><td>5.3</td><td>1.35</td><td>0.092</td><td>6.81</td></tr>
<tr><td>Sand (0.89 mg/L)</td><td>5.3</td><td>1.35</td><td>0.059</td><td>4.35</td></tr>
<tr><td>Loamy silt</td><td>7.1</td><td>0.95</td><td>0.060</td><td>6.34</td></tr>
<tr><td>Silty sand</td><td>5.8</td><td>1.35</td><td>0</td><td>0</td></tr>
</table>
No pH dependence
For modelling to EPA methodology, the lowest non-sand value is applied, which in this case is a Kd of 0.060 L/kg and a Koc of 6.34 L/kg.
</td><td>EFSA, 2010</td></tr>
</table>

<table>
<tr><th>Test type</th><th>Value</th><th>Reference</th></tr>
<tr><td>Mobility in soil</td><td>
Column leaching:
Eluation (mm): 200 mm; Time period (d): 2 d; 0.13 – 2.8 % active substance in leachate.
Lysimeter/field leaching studies:
Location: SLFA Neustadt/Weinstrasse, Germany
Study type: 2 lysimeters
Soil properties: sandy loam, pH = 7.3, OC= 0.9%
Number of applications: 1 application per year
Dates of application: May 15, 1991; April 23, 1992
Crop rotation: 1st year: winter wheat, rape, winter barley, 2nd year: rape, 3rd year: sugar beets.
Duration:
Application rate: 1st year: 94.3 kg cyanamide/ha; 2nd year: 91 kg a.s./ha; (non-radiolabelled cyanamide)
Average annual rainfall (mm): 1st year 820; 2nd year 863.8; 3rd year 926.2
Average annual leachate volume: 223 L.
Concentrations of cyanamide in percolate:
<table>
<tr><td></td><td>Lysimeter</td><td>leachate (µg/L)</td><td>leachate (L)</td></tr>
<tr><td rowspan="2">1st year</td><td>L9</td><td>< 0.03</td><td>199.1</td></tr>
<tr><td>L10</td><td>< 0.02</td><td>174.8</td></tr>
<tr><td rowspan="2">2nd year</td><td>L9</td><td>< 0.03</td><td>236.0</td></tr>
<tr><td>L10</td><td>< 0.02</td><td>202.6</td></tr>
<tr><td rowspan="2">3rd year</td><td>L9</td><td>< 0.02</td><td>268.0</td></tr>
<tr><td>L10</td><td>< 0.02</td><td>258.6</td></tr>
</table>
Concentrations of cyanamide in soil:
<table>
<tr><td></td><td>Lysimeter</td><td>mg/kg</td><td>Soil layer</td></tr>
<tr><td rowspan="2">1st year</td><td>L9</td><td><0.05</td><td>0-30 cm</td></tr>
<tr><td>L10</td><td><0.05</td><td>0-30 cm</td></tr>
<tr><td rowspan="2">2nd year</td><td>L9</td><td><0.05</td><td>0-30 cm</td></tr>
<tr><td>L10</td><td><0.05</td><td>0-30 cm</td></tr>
<tr><td rowspan="4">3rd year</td><td>L9</td><td><0.05</td><td>0-30 cm</td></tr>
<tr><td>L9</td><td><0.05</td><td>30-110 cm</td></tr>
<tr><td>L10</td><td><0.05</td><td>0-30 cm</td></tr>
<tr><td>L10</td><td><0.05</td><td>30-110 cm</td></tr>
</table>
</td><td>EFSA, 2010</td></tr>
<tr><td>Field dissipation</td><td>No data.</td><td></td></tr>
</table>

In soil laboratory incubations under aerobic conditions in the dark, cyanamide exhibited very low to low persistence. The formation of unextractable residues was a minimal sink, accounting for max. 9.5% AR, but only 5.6% AR at the end of the study; the mineralisation to carbon dioxide was an extremely significant sink, accounting for 94.6 % AR after 14 days, at the end of the study. No metabolites or transformation products were formed that would trigger further evaluations. Under anaerobic conditions the mineralisation to carbon dioxide was also a significant sink, accounting for 53.1 % AR after 60 days. The formation of unextractable residues accounted for 6.9 % AR after 60 days. In a soil photolysis study, where thin layer soil samples were irradiated, two major (>10% applied radioactivity (AR)) transformation products were formed. In another soil photolysis study, where thicker soil layers were used, these transformation products were also found, but at lower levels. Cyanamide exhibited very high mobility in soil.

PLEASE NOTE, the half-life results from laboratory soil metabolism studies are non-normalised. While EFSA (2010) does provide normalised half-lives, these are not applied in the New Zealand assessment as there are not reference soil moisture and temperature conditions in different regions in New Zealand for which to undertake the necessary transformation calculations. Non-normalised values, therefore, provide a more appropriate assessment.

Degradation and fate of cyanamide in the aquatic environment

Information on the degradation and fate of cyanamide in the aquatic environment is summarised in Table 4. Information on bioaccumulation potential is listed in Table 5.

Table 4: Degradation and fate in aquatic environments

<table>
<tr><th>Test type</th><th>Value</th><th>Reference</th></tr>
<tr><td>Hydrolysis</td><td>pH 5: 1200 d at 22 °C;
pH 7: 2300 d at 22 °C;
pH 9: 810 d at 22 °C</td><td>EFSA, 2010</td></tr>
<tr><td>Aqueous photolysis</td><td>DT_{50} : 28.9 d (pH 5), 38.5 d (pH 7), irradiated with artificial light from Xenon lamp (290-400 nm)
DT_{50} 116 d (pH 5), 139 d (pH 7) in non-irradiated control
Metabolite: Urea: 12.2 % of initial measured dose after 30 days</td><td>EFSA, 2010</td></tr>
<tr><td>Degradation in water/sediment</td><td><table>
<tr><th>System</th><th>Phase</th><th>T (ºC)</th><th>DT_{50} [d]</th><th>DT_{90} [d]</th><th>Kinetic model</th></tr>
<tr><td rowspan="3">River</td><td>Water</td><td>20</td><td>2.3</td><td>7.7</td><td>SFO</td></tr>
<tr><td>Sediment</td><td>20</td><td>-</td><td>-</td><td></td></tr>
<tr><td>Whole system</td><td>20</td><td>2.5</td><td>8.2</td><td>SFO</td></tr>
<tr><td rowspan="3">Pond</td><td>Water</td><td>20</td><td>4.3</td><td>14.4</td><td>SFO</td></tr>
<tr><td>Sediment</td><td>20</td><td>-</td><td>-</td><td></td></tr>
<tr><td>Whole system</td><td>20</td><td>4.8</td><td>15.8</td><td>SFO</td></tr>
</table>
83.5%-86.1% mineralisation at study end (28 d);
6.0%-11.0% non extractable residues after study end (28 d);
Maximum non extractable residues in sediment 7.8% (21 d) to 11% (28 d).
Geomean model DT_{50}: 3.1 d (water), 3.5 d (whole system).</td><td>EFSA, 2010</td></tr>
<tr><td>Readily biodegradable</td><td>Not ready biodegradable.</td><td>EFSA, 2010</td></tr>
</table>

Table 5: Bioaccumulation potential

Test type	Value	Reference
Partition coefficient octanol/water	log P_{OW} = -0.72	EFSA, 2010
Fish bioconcentration (Whole fish)	No data (not necessary given the low LogPow).	EFSA, 2010

Cyanamide is stable to hydrolysis, however the degradation in the irradiated samples of the aqueous photolysis study was faster than in the dark control, and urea as a major transformation product was formed. In laboratory incubations in aerobic natural water sediment systems in the dark, cyanamide exhibited relatively low persistence (single first-order DT50 2.5 - 4.8 days), forming the major metabolite urea. The partition of cyanamide to the sediment was not significant (≤ 4.7% AR). Mineralisation to carbon dioxide was significant, accounting for 84 - 86% AR, while residues not extracted from the sediment represented 6 - 11% AR at the end of the study.

Cyanamide is not readily biodegradable. It is not expected to bioconcentrate.

4 Ecotoxicity

Aquatic toxicity

Table 6 contains the acute and chronic aquatic toxicity test results for cyanamide. These results are the most sensitive only for each group as reported in EFSA (2010) and cross checked with US EPA (2014a). There are significant differences in the end-points reported from both these source documents. An additional cross check with the US EPA Office of Pesticide Prevention database (available at https://ecotox.ipmcenters.org/) indicates that the tests reviewed by both regulators are the same so it is unclear why the interpretation was so different. As an example, the fish study with bluegill sunfish is reported to be based on 100% active by the US EPA, and on a formulation by EFSA resulting in LC50 values of 88 mg ac/L and 43.1 mg/L respectively. In both cases, the test was undertaken in 1985, so it is expected it is the same result, and EFSA reports the LC50 as 88 mg formulation/L.

All the tests relied on were performed prior to the New Zealand EPA initial reassessment of cyanamide, so none are likely to constitute new information. However, it is not known what values the NZ EPA used in their assessment.

Table 6: Summary of aquatic toxicity data for cyanamide (most sensitive from EFSA, 2010 and US EPA, 2014).

Species	Study type, duration and result	Reference
	Fish acute toxicity	
Rainbow trout, *Oncorhynchus mykiss*	96h, flow-through, not stated whether nominal or measured. Test with 49% ai formulation. LC50 45.3 mg ac/L	US EPA, 2014a with additional information from OPP database.
Bluegill sunfish, *Lepomis macrochirus*	96h, flow-through, not stated whether nominal or measured. Formulation code LH 21 810 A **LC50 43.1 mg ac/L**	EFSA, 2010
	Fish chronic toxicity	
Rainbow trout, *Oncorhynchus mykiss*	21d flow-through, not stated whether nominal or measured. Formulation code LH 21 810 A **NOEC 3.7 mg ac/L**	EFSA, 2010
	Aquatic invertebrates acute toxicity	
Daphnia magna	48-hr static, not stated whether nominal or measured. 49% ac formulation EC50 3.2 mg ac/L	EFSA, 2010; US EPA, 2014a
Eastern Oyster, *Crassostrea virginica*	96-hr flow through, measured concentrations. Active constituent **EC50 2.3 mg ac/L**	US EPA, 2014a
	Aquatic invertebrates chronic toxicity	
Daphnia magna	21-day flow-through. not stated whether nominal or measured. 50% ac formulation. **NOEC 0.10 mg ac/L** (Growth - length)	EFSA, 2010 US EPA, 2014a

Species	Study type, duration and result	Reference
Sediment organisms chronic toxicity		
Chironomus riparius	28 d assumed spiked water, nominal concentrations. 51.1% w/w formulation **NOEC 6.6 mg ac/L** (development)	EFSA, 2010
Algae and aquatic plant toxicity		
Pseudokirchneriella subcapitata	96 h static, nominal concentrations. 51.1% w/w formulation 96 h ErC50 16.6 mg ac/L	EFSA, 2010
Anabaena flos-aquae	72 h static, nominal concentrations. 51.1% w/w formulation **72 h ErC50 0.65 mg ac/L**	EFSA, 2010
Lemna gibba	7d static, not stated whether nominal or measured. 51.1% w/w formulation ErC50 5.7 mg ac/L	EFSA, 2010
Outdoor mesocosm study		
Zooplankton, macroinvertebrates, phytoplankton, periphyton and macrophytes	12 week (86 day) Ecological Threshold Option regulatory acceptable concentration (ETO-RAC) **0.1 mg/L** No pronounced effects (Class 3A or higher). ETO-RAC considered protective for all populations tested.	Hommen, 2019.

From standard single species and water only studies, the most sensitive result was the chronic (21 d) test with *Daphnia magna* where a NOEC of 0.1 mg/L was determined. This concentration was confirmed in the outdoor mesocosm study. However, that study tested effects on populations of a large number of organisms over a longer time period so allows greater confidence in the value and therefore, a reduction in assessment factors applied in the assessment. Table 9 of EPA (2020) provides levels of concern (LOC) and where chronic values are applied, the LOC for non-threatened and threatened species of aquatic organisms is 1.0 and 0.1, respectively. This equates to an assessment factor of 1.0 and 10, respectively, applied to the NOEC of the critical study. EPA (2020) notes that the trigger values in Table 9 may be increased if information on multiple species is available and this can therefore be applied to the end-point of the mesocosm study given the large number of species tested. While EPA (2020) does not provide guidance on the actual increase in the trigger value (which will be based on a decrease in the assessment factor), guidance is available in EFSA (2013). It is not possible to decrease the assessment factor for non-threatened species, but the factor of 10 for threatened species could be relaxed. EFSA (2013) recommends adjustments of assessment factors based on certain effect classes. For chronic exposure, where the outcomes are based on nominal or peak concentrations and the ETO-RAC is set for Effect Class 2 concentrations (as is the case for the mesocosm study), the assessment factor can be adjusted from 10 to 2-3. Taking the more conservative option of 3, the LOC can be adjusted from 0.1 to 0.3 for the protection of threatened species in the aquatic assessment. This will be applied in any refinement required for the aquatic risk assessment.

Terrestrial vertebrate toxicity

Table 7 contains the acute and chronic avian toxicity test results for the active ingredient cyanamide. Values in bold are those used for the risk assessment.

Table 7: Summary of terrestrial vertebrate toxicity data for cyanamide

Test species	Test type, duration and result	Reference
Bobwhite quail, *Colinus virginianus*	Acute oral LD50 **LD50 350 mg ac/kg bw**	EFSA, 2010
	8 day dietary; LDD50 >1042 mg/kg bw/d	EFSA, 2010
	Reproduction, 1 generation, 22 weeks **NOEC 152 mg ac/kg diet** **(13.3 mg ac/kg bw/day)**	EFSA, 2010
Mallard duck, *Anas platyrhynchos*	Acute oral LD50 No data	
	8 day dietary; LDD50 >435 mg/kg bw/d	EFSA, 2010
	Reproduction, 1 generation, 22 weeks No data	

Environmental risk assessment – aquatic environment

The exposure calculations and corresponding risk quotients for this assessment have been undertaken with the PERAMNZ software[1], designed specifically for New Zealand EPA assessment methodologies. However, NZ undertakes as their first tier of aquatic assessment, an analysis using GENEEC2. GENEEC2 was the US EPA default screening model but is no longer supported by the US EPA. The executable file for this package is not easily run on current computer systems as it has not been updated for considerable time. Further, the algorithms and methodology used to obtain GENEEC2 outputs are not available so can’t be replicated. Finally, the default water depth in GENEEC is 2 m, which is considerably deeper than the default 30 cm water depth otherwise applied by NZ EPA.

PERAMNZ, therefore, adopts the FOCUS Step 1 calculation approach, which is transparent and can be amended to include the default NZ environment values as required. The algorithms are provided in Appendix I (Steps 1-2 In Focus User Manual) of the European FOCUS surface water scenarios (Linders et al, 2003). That document should be consulted for a full description of the model equations and methodology.

For the lowest chronic toxicity value (*Daphnia magna*) performed in a 21 d flow through system, a TWA_{21} factor of 0.32 is calculated again, assuming no degradation/dissipation on the first day following application. No TWA is considered for acute exposure as the most sensitive result (ErC50 for the cyanobacteria, *Anabaena flos-aquae*) was determined in a static test system. This value is applied in the screening assessment. For refinement of the aquatic risk assessment, the final end-point applied is the ETO-RAC (0.1 mg ac/L) with an adjusted level of concern with rationale described below.

Calculation of expected environmental concentrations

The following input values are used in modelling surface water concentrations for the highest exposure scenario from the uses described in **Table 1**, namely, application at 48 L product/ha (6 L/100 L spray volume; 800 L spray volume per hectare). A single application is modelled.

[1] **P**esticide **E**nvironmental **R**isk **A**ssessment **M**odel for **N**ew **Z**ealand, Beta v1, © Australian Environment Agency Pty Ltd, 2018.

Table 8: Input parameters for PERAMNZ analysis

Parameter	Cyanamide
Crop(s)	Kiwifruit
Application rate (kg/ha)	25
Application frequency	1
Application interval (days)	-
Kd	0.06 L/kg (lowest non-sand result)
Aerobic soil DT_{50} (days)	1.4 (80^{th} percentile, field values)
Aquatic DT_{50} (days)	4.8 (longest whole system half-life)
Water TWA_4 fraction	0.32 (chronic) This value is not applied in the FOCUS Step 1 calculations.
Methods of application	High volume sprayer

Output from the screening FOCUS Step 1 method

With the use pattern in field crops, a drift factor of 2.77% is applied as a default. Runoff of 10% is assumed as a default in these Step 1 calculations. The algorithms are available in Appendix 1 of Linders *et al* (2003). In undertaking these calculations, a water depth of 30 cm overlying sediment of 5 cm depth is applied. The density of the sediment was selected to be 0.8 g/cm^2 and an organic carbon content of 5%. The water body is assumed to have an area equivalent to one tenth of the field from which it receives run-off or drainage water (a field:water ratio of 10). Assuming a 1 ha field, the 0.1 ha (1000 m^2) water body will have a volume of 3 x 10^5 litres. While FOCUS Step 1 methodology usually considers peak water concentrations based on a single event, if the interval between two applications is below three times the DT_{50} of the compound, the input will be accumulated dependent on the number of applications per season. Only a single application is modelled in this assessment.

Table 9: Estimated environmental concentrations, FOCUS Step 1

CYANAMIDE

Parent			
Application Rate (g ac/ha)	24960	Plant Interception (Percent)	0
Kd	0.06	Drift Factor:	0.0277
		Water DT50 (days)	4.8
		Sediment DT50 (days)	

Input via drift (mg/m2)	69.139
Input via runoff (mg/m2)	2,496
Fraction entering water body in water phase	0.992
Fraction entering water body in sediment phase	0.008

ESTIMATED ENVIRONMENTAL CONCENTRATIONS

	Peak	4 d TWA	21 d TWA	60 d TWA	100 d TWA
Water (µg/L)	8,484.4	6,531.0	2,829.0	1,086.5	660.1
Sediment (mg/kg dw)	0.50				

Tuesday, 21 April 2020 PERAMNZ v1.0

Calculated Step 1 risk quotients

Table 10: Acute risk quotients for water column species and risk conclusions for Cyanamide

Species	Peak EEC from FOCUS Step 1 (mg/L)	LC50 or EC50 (mg/L)	Acute RQ	Conclusion
Fish, *Lepomis macrochirus*	8.48	43.1	0.20	Risks ABOVE LOC Risks ABOVE LOC, Threatened species
Invertebrates, *Crassostrea virginica*	8.48	2.3	3.69	Risks ABOVE LOC Risks ABOVE LOC, Threatened species
Algae, *Pseudokirchneriella subcapitata*	8.48	16.6	0.51	Risks ABOVE LOC
Algae, *Anabaena flos-aquae*	8.48	0.65	13.1	Risks ABOVE LOC
Aquatic plants, *Lemna gibba*	8.48	5.7	1.49	Risks ABOVE LOC Risks ABOVE LOC, Threatened species

Table 11: Chronic risk quotients for water column species and risk conclusions for Cyanamide

Species	Relevant EEC from FOCUS Step 1 (mg/L)	NOEC (mg/L)	Chronic RQ	Conclusion
Fish, *Oncorhynchus mykiss*	1.1	3.7	0.29	Risks below LOC Risks ABOVE LOC, Threatened species
Invertebrates, *Daphnia magna*	2.83	0.1	28.3	Risks ABOVE LOC Risks ABOVE LOC, Threatened species
Invertebrates, *Chironomus riparius*	2.83	6.6	0.43	Risks below LOC Risks ABOVE LOC, Threatened species

While *Chironomus riparius* is a standard sediment organism, the only toxicity data are from exposure through the water column. Cyanamide is not expected to partition to sediment. Consequently, this species has been included in the water column assessment.

At this first step of assessment, there is an identified risk to fish, aquatic invertebrates, algae and aquatic plants for both acute and chronic exposure. Consequently, further refinements are required.

Refinement of the aquatic risk assessment

Predicted exposures are above the LOC for threatened species of fish, aquatic invertebrates and sediment organisms based on chronic exposure toxicity end-points. The scenario modelled is a worst-case using the maximum application rate. Because risks were identified further modelling was performed to consider whether buffer zones may be able to mitigate risks from spray drift and runoff.

Spray drift

The EPA applies the AgDrift model to calculate downwind buffer zones. The drift curves are those that were applied by the APVMA from 2010 until their recent policy update in 2019. Zespri measured downwind spray drift for several different nozzle types and spray equipment when applied to dormant kiwifruit vines. These data will be supplied separately. However, the recommendation from these trials is that application should occur using air induction (AI) nozzles and the addition of an adjuvant (NU0017). The following measured 90th percentile deposition rates from all the AI nozzle trials against those from the EPA vineyards and sparse orchard curves to determine whether either of these are appropriate for the kiwifruit assessment:

Table 12: Deposition fractions at different downwind distance for EPA drift curves and Zespri measured data. Values in brackets represent the overestimation of the Zespri data by the EPA deposition curves.

Distance downwind (m)	EPA Vineyards	EPA Sparse Orchard	Zespri measured 90th percent deposition
9	0.01144 (1.3)	0.245962 (29)	0.008569
13	0.00709 (1.5)	0.14474 (31)	0.00473
17	0.004962 (1.5)	0.093023 (29)	0.003329

These results show that the EPA vineyards scenario overestimated the Zespri measured drift by 1.3-1.5 times, which is in relatively good agreement. However, the sparse orchard is inappropriate as it consistently overestimated the drift by around 30 times. The limited evidence suggests that as distances move closer to the edge of the field, spray to dormant kiwifruit will increase relative to that from the vineyard curve as the ratio of vineyard:kiwifruit is lower at 9 m than at 13 and 17 m.

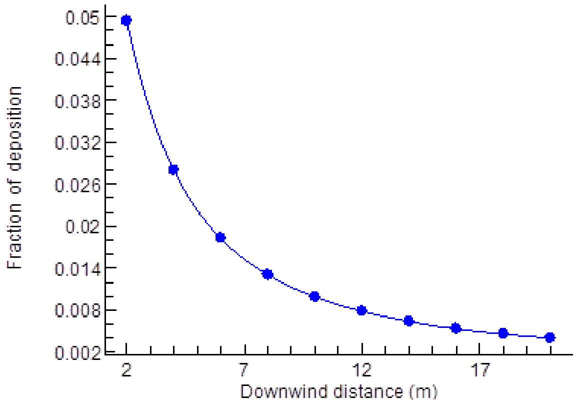
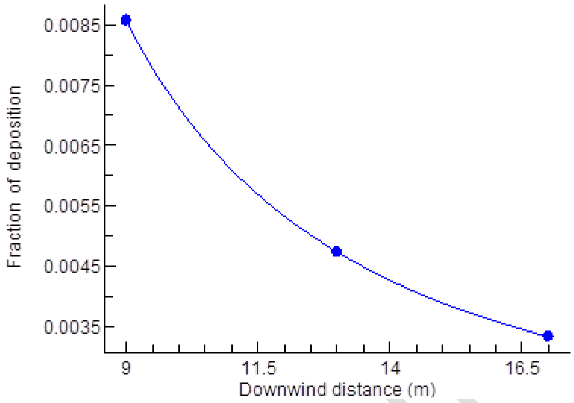
The next part of this analysis considers appropriate models to extrapolate the Zespri data closer into the field and further out from the 17 m measured. This has been done by determining a best fit curve for both data sets then performing the extrapolation for the Zespri data. The curve fitting has been undertaken with XLfit v 5.4.0.8 (ID Business Solutions Limited). The analysis has been performed starting from 2 m out to 20 m from the edge of the field and is as follows:

1) Identify a common model for both data sets that will allow prediction of spray drift to kiwifruit close to the edge of the field.

Several models were tested and, while they showed excellent correlation to the vineyard data set and the limited data set for kiwifruit from 9-13 m, they were not suitable for extrapolation closer to the field as the equations would predict >>100% deposition which is not possible. The model chosen was a 2-phase exponential decline model with the following equation:

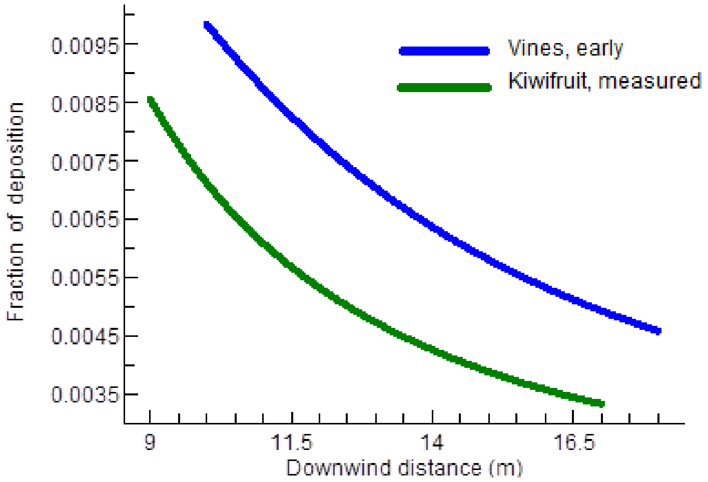
Fit (fraction of deposition) = ((E+(A*exp(((-1)*B)*x)))+(C*exp(((-1)*D)*x)))
where x = downwind distance (m).

Table 13: Final equations for predicting downwind buffer zones based on fraction of deposition – AgDrift vineyards and dormant kiwifruit

EPA AgDrift, vineyards deposition, 2-20 m	**Zespri 90th percent deposition, AI + NU0017, 9-17 m**
	
A = 0.033197 B = 0.153955 C = 0.066691 D = 0.543404 E = 0.002482	A = 0.030203 B = 0.191821 C = 0.449492 D = 0.657492 E = 0.002166

The following figure shows the overlay between the AgDrift vineyard and the measured kiwifruit deposition over the distance of 9 to 18 m for a direct comparison:

Figure 1: Deposition curves for Vineyards (AgDrift) and Dormant Kiwifruit (measured), 9-18 m downwind.

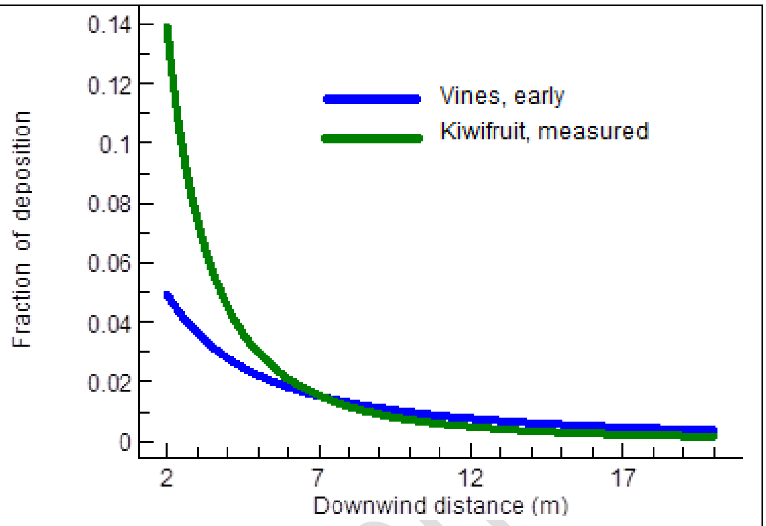


2) Extrapolate the kiwifruit deposition data to obtain a deposition curve applicable to application to dormant kiwifruit using AI nozzles and the addition of NU0017.

Applying the curve equation for kiwifruit, the following deposition fractions are calculated from 2-20 m:

Table 14: Comparison of deposition curves for vineyards (EPA, AgDrift) and kiwifruit (dormant, 90%ile, extrapolated).

Downwind distance (m)	EPA Vineyards, AgDrift	Dormant Kiwifruit (AI nozzles + NU0017)
2	0.04937766	0.139157297
4	0.027982962	0.04633731
6	0.018261684	0.019528636
8	0.013020492	0.010698406
10	0.009861552	0.007125632
12	0.007801959	0.005324172
14	0.006378234	0.004260623
16	0.005348466	0.003578401
18	0.004576263	0.003124545
20	0.003979902	0.002818147



While the curve is extrapolated, it is possible the deposition closer to the field edge from application to dormant kiwifruit exceeds that predicted by the EPA vineyard curve while the measured data from 9-17 m show the vineyard curve overpredicts deposition. For the spray drift assessment, the kiwifruit derived curve will be applied with a direct comparison to the EPA's vineyard curve.

Only a chronic value is assessed (mesocosm ETC-RAC = 0.1 mg/L) with an assessment factor of 3 for threatened species. This is justified because the end-point is based on an assessment of effects over a full 12 week period which included observations over a more acute time frame, starting at 6 days after application.

Table 15: Input parameters and calculation of spray drift buffer zone for the refined risk assessment

Input parameter	Value	
Crop	Kiwifruit	
Application rate (g ac/ha)	24960	
Number of applications	1	
Application interval (d)	Not applicable	
Koc (L/kg)	6.34	
DT_{50} (days, soil)	1.4	
DT_{50} (days, water)	4.8 (whole system)	
Application method	Kiwifruit, dormant application, AI nozzles + NU0017.	High volume, vertical sprayers (Vineyard).
Environmental compartment	Water	Water
Toxicity end-point	0.10 mg/L	0.10 mg/L
Assessment factor	3	3
Exposure period (days)	86 (time for mesocosm study)	
Fraction of deposition	0.04421 (calculated to EPA methodology)	
Buffer zone (m)	6 metres (Drift fraction 0.0195)	4 metres (Drift fraction 0.0280)

A downwind buffer zone of 6 m is required to protect threatened species (aquatic invertebrates) from exposure to cyanamide from spray drift events when modelled using the kiwifruit dormant application curve, or 4 metres when using the vineyard scenario. A spray drift buffer zone of 6 metres is recommended.

Runoff

The following runoff assessment is based on the modelling approach described in EPA (2020). There are concerns about the validity of some of the input parameters as defaulted to by the EPA, particularly the use of fixed rainfall and runoff values of 100 mm and 20 mm respectively and not being able to adequately address differences in soil types. Nonetheless, to comply with the EPA methodology the approach as described in the consultation document has been implemented.

As the ecotoxicity end-point is based on a long term mesocosm study with populations from a range of aquatic organisms, the runoff risk assessment is only undertaken for this end-point without a separate acute toxicity end-point considered. The threatened species level of concern is adjusted from 0.1 to 0.3. This runoff methodology assesses for concentrations in the dissolved phase and assumes three days prior to the runoff event. No time weighted average factor has been applied for chronic exposure as the mesocosm result is based on nominal values.

The following results are calculated:

Table 16: Input parameters and calculation of runoff buffer zone for the screening runoff risk assessment

Input parameters		Parent
Application Rate (g ac/ha)		25000
Number of applications		1
Interval between applications (days)		365.000
Soil half-life (days)		1.4
Multiple application factor:		1.000
Kd (L/kg)		0.0634
Default Buffer zone (m)		0
Slope factor		0.49
Plant Interception (Fraction)		0
Rainfall (mm)		100.0
Runoff (mm)		20.0
Heterogeniety Factor		0.5000
Runoff (% of active, EPA)		1.0465
PEC water (µg/L)	1,308	1,308

Species	ACUTE	CHRONIC
Toxicity end-point (mg/L)	0.65	0.1
Risk Quotient	2.013	13.082
TWA factor	1.000	1.000

	Buffer zone required (m)	
Non-threatened species		14
Threatened species		20

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Refinement options

The above result is based on the default slope factor of 0.5 (12.5% slope). Kiwifruit is a horticultural crop where 80% is grown in the Bay of Plenty. Other product regions include Northland (Kerikeri & Whangarei), South Auckland, Waikato (Cambridge), Gisborne, Hawkes Bay and Nelson. In order to consider the expected slopes within the growing areas of these regions additional information has been through Manaaki

Whenua – Landcare Research, specifically applying map layers for intensive horticulture and steepness of slope[2]. Horticulture growing areas in the specified regions have been mapped (broadly) and an analysis of slopes in these regions undertaken. The mapped areas are shown in Appendix 1. The following table summarises the results:

Table 17: Slope analysis – Kiwifruit growing regions

Region	Centre	Horticulture growing area mapped (ha)	Proportion of area mapped		Approximate horticulture area per slope class (ha)	
			0-3^o slope	4-7^o slope	0-3^o slope	4-7^o slope
Northland	Kerikeri	1142	0.71	0.31	811	354
Waikato	Cambridge	81391	0.94	0.044	76508	3581
Bay of Plenty	Waihi	3432	0.94	0.074	3226	254
Bay of Plenty	Te Puke	13646	1		13646	0
Bay of Plenty	Te Puke	5748	0.78	0.19	4483	1092
Bay of Plenty	Edgecumbe	20796	1		20796	0
Bay of Plenty	Opotiki	4334	0.93	0.075	4031	325
Gisborne	Gisborne	5739	0.96	0.034	5509	195
Hawkes Bay	Hastings	15770	0.982	0.018	15486	284
Nelson	Nelson	3397	0.985	0.014	3346	48
TOTAL		**155395**			**147842**	**6133**

This analysis covers ~155,000 hectares of horticultural growing areas in the 6 regions assessed of which >95% is grown on slopes of 0-3^0 (0-5%). Within the Bay of Plenty centres considered, almost 50,000 hectares of horticulture area was analysed with >96% grown on slopes ≤5%. It is reasonable, therefore, to reduce the slope in the runoff modelling from 12.5% to 5%. The following outcome is modelled:

2 https://ourenvironment.scinfo.org.nz/maps-and-tools/app/

Table 18: Input parameters and calculation of runoff buffer zone for the refined runoff risk assessment

Input parameters		Parent
Application Rate (g ac/ha)		25000
Number of applications		1
Interval between applications (days)		365.000
Soil half-life (days)		1.4
Multiple application factor:		1.000
Kd (L/kg)		0.0634
Default Buffer zone (m)		0
Slope factor		0.14
Plant Interception (Fraction)		0
Rainfall (mm)		100.0
Runoff (mm)		20.0
Heterogeniety Factor		0.5000
Runoff (% of active, EPA)		0.3050
PEC water (µg/L)	381	381

Species	ACUTE	CHRONIC
Toxicity end-point (mg/L)		0.1
Risk Quotient		3.812
TWA factor		1.000
	Buffer zone required (m)	
Non-threatened species		7
Threatened species		14

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The risk to aquatic organisms is acceptable provided a buffer zone of 14 m is applied to downslope water bodies.

Groundwater risk assessment

The predicted concentration of the individual active constituents in ground water, calculated using the Sci-Grow model, is shown in Table 19 with application to onions as the worst case. The concentration is initially compared to the EU limit for the maximum permissible concentration of pesticide active ingredients and their relevant metabolites of 0.1 µg/L.

Table 19: Input parameters for Sci-Grow analysis and resulting PEC values

Input parameters	Cyanamide
Application rate (kg a.i./ha)	25
Number of applications	1
Koc	6.34
Aerobic soil DT_{50} (days)	1.4
PEC_{gw} (µg/L)	0.05

1) The application rate is conversion from kg a.i./ha to lb/acre (the units required to be entered into the model) by multiplying it by 0.892.

The model predicts a PEC below the level of concern of 0.1 µg/L. Therefore, the risk for groundwater contamination is acceptable.

Bird risk assessment

The bird risk assessment is based on a comparison of the PEC with toxicity values for the substance. The toxicity value is divided by the PEC to give a Toxicity Exposure Ratio (TER). However, to enable a comparison with NZ EPA levels of concern, the TER is converted to a risk quotient in this assessment.

Predicted exposure under the bird acute and long-term dietary screening assessment is shown in the following table.

Table 20: Exposure of birds for screening assessment, Exposure scenario 1

Screening type[1]	**Indicator species**[2]	**Application rate (kg/ha)**	**Short-cut value (90^{th}%)**[3]	**TWA**[4]	**MAF (90^{th} %)**[5]	**Number of applications**	**Daily dietary dose (DDD)**
Vineyard crop with 1 application.							
Acute	Small omnivorous bird	25	95.3	1.0	1.0	1	2382
Reproduction			38.9	0.53	1.0	1	515

1 EFSA, 2009, Table 5 p27
2 EFSA, 2009, Table 6 p28
3 90th %ile short-cut value used for the acute assessment, mean value used for the reproduction assessment. EFSA, 2009, Table 6 p28
4 The exposure assessment of the reproduction assessment uses time-weighted average (TWA) exposure estimates over 1, 2, 3 or 21 days for different phases of the assessment. 1 day = 1.0; 2 days = 0.93; 3 days = 0.9; 21 days = 0.53. EFSA, 2009, Table 11 p34.
5 90th %ile MAF value used for the acute assessment, mean value used for the reproduction assessment. EFSA, 2009, calculated as per Appendix H, EFSA, 2009.

From the exposure calculations, the following risk quotients are determined:

Table 21: RQ value for acute dietary risk assessment

Assessment type	**Generic focal species**	**DDD**	**Toxicity endpoint value (mg/kg bw/d)**	**RQ**	**Conclusion**
Vineyard crop with 1 application.					
Acute	Small omnivorous bird	2382	350	6.79	**Risks ABOVE LOC**
Long term		515	13.3	38.7	**Risks ABOVE LOC, Threatened species.**

A potential risk is identified to birds from both acute and chronic exposure. A tier 1 risk assessment is performed based on EFSA (2009), but without inclusion of single diet values. Further, because of the timing of application while vines are dormant, only the early growth stage exposures are considered. The following outcomes are calculated:

Table 22: RQ value for acute risk assessment – Tier 1 assessment; TWA = 1, MAF = 1.

Crops and BBCH class	Generic focal species	Short cut value	Toxicity endpoint (mg/kg bw/d)	RQ	Conclusion
Kiwifruit vines (based on Vineyard scenario), 1 application at 25 kg ac/ha.					
BBCH 10 - 19	**Small insectivorous species "Redstart"**	27.4	350	1.95	**Risks ABOVE LOC** **Risks ABOVE LOC, Threatened species**
BBCH 10 - 19	**Small granivorous bird "Finch"**	14.8	350	1.06	
BBCH 10 - 19	**Small omnivorous bird "lark"**	14.4	350	1.03	

The acute Tier 1 risk assessment indicates risks above the level of concern to both threatened and non-threatened birds from the use of cyanamide in vineyards.

Table 23: RQ value for chronic risk assessment – Tier 1 assessment; TWA = 0.53, MAF = 1.

Crops and BBCH class	Generic focal species	Short cut value	Toxicity endpoint (mg/kg bw/d)	RQ	Conclusion
Kiwifruit vines (based on Vineyard scenario), 1 application at 25 kg ac/ha.					
BBCH 10 - 19	**Small insectivorous species "Redstart"**	11.5	13.3	11.4	**Risks ABOVE LOC** **Risks ABOVE LOC, Threatened species**
BBCH 10 - 19	**Small granivorous bird "Finch"**	6.9	13.3	6.86	
BBCH 10 - 19	**Small omnivorous bird "lark"**	6.5	13.3	6.47	

The chronic Tier 1 risk assessment indicates risks above the level of concern to both threatened and non-threatened birds from the use of cyanamide in vineyards.

Arguments for refining the risk assessment to birds

Discussion on acute toxicity value

The updated EFSA conclusion, and underlying Draft Assessment Report, describes a field study assessing avian impacts described below. Despite the tier 1 assessment identifying a potentially high acute risk to birds, significant adverse impacts in the field were not identified.

There are several reasons why this may be the case:

- Doses in the acute oral toxicity studies are administered as one large dose. In the field, most birds continuously feed throughout the day (Moore et al, 2014);
- Based on information for other vertebrates (mammals) cyanamide is almost completely absorbed following oral dosing but is rapidly metabolised with a half-life of approximately 1 hour (EU Draft Assessment Report, Volume 3, Annex B, B.6, part 1, 2006 assessment). Therefore, when feeding

throughout the day, birds have the opportunity to detoxify and/or eliminate cyanamide before it accumulates to internal doses that result in lethality;

- When pesticides are mixed with food, or when consumed at a time when the gastro-intestinal (GI) tract has other food items present, they are absorbed less efficiently than when dosed as a bolus in pure form into an empty GI tract (Lehman-McKeeman, 2008).

While these arguments are applicable to interpreting the results of the field study with the acute oral LD50 of 350 mg/kg bw, they also assist putting the dietary toxicity study results into perspective. Bobwhite quail were fed a diet for 5 days containing cyanamide in the feed at 312.5 to 5000 mg/kg diet (reported in EU Draft Assessment Report, Volume 3, Annex B, B.9, 2006 assessment). This was a no choice test and there were no effects on feed consumption or body weights. This means food was not avoided so exposure definitely occurred. The highest test concentration equated to a daily exposure of 1042 mg/kg bw/d and no mortalities were recorded. Therefore, a dietary LC50 can't be determined, but would be anticipated to significantly exceed the acute oral LD50.

Given these arguments and data, additional refinements are proposed to the bird diets currently assessed at the Tier 1 assessment level as per EFSA (2009).

Proposed revised bird exposure modelling

For kiwifruit, application will occur in winter to dormant vines. The following diets are assessed in EFSA (2009) for the vineyard scenario at Tier 1 for BBCH 10-19, which are most likely to coincide with this use pattern:

Table 24: Generic focal species, diet guild and diet composition for Tier 1 assessment.

Generic focal species	Diet guild	Foraging strata	Diet of generic focal species in crop (%)
Small insectivorous bird	Insectivorous	Foliar/Ground	50% ground arthropods; 50% foliar arthropods.
Small granivorous bird	Granivorous	Ground	100% weed seeds.
Small omnivorous bird	Omnivorous	Ground	25% crop leaves; 25% weed seeds; 50% ground arthropods.

In these diets, ground invertebrates are assessed based on residues without crop interception given the dormant nature of vines at the time of application.

Table 22 above provides the generic focal species and shortcut values for these different feeding guilds. The shortcut values provided in this table are the sum of the food intake rate/body weight (FIR/bw) of the bird and the residues level. Where mixed diets are assessed, the food intake rate differs to a single food source diet because different food items have different energy levels and moisture contents, and the energy is assimilated at different rates.

The timing of application is important in this refinement because, for these generic focal species, certain food items will simply not be available. With application to dormant crops, foliar arthropods will not be present and insectivorous birds will need to source these from other areas. Similarly, crop leaves will not be present for omnivorous birds so again, that diet component will require sourcing from elsewhere.

Weed seeds are also unlikely to be present given the application in winter. In their guide on weed life cycles and considering annual weeds (both summer and winter annuals), biennial weeds and perennial weeds, the University of Massachusetts Centre for Agriculture does not describe any that are likely to set seed in winter.[3] Summer annual weeds grow, flower, produce seed, and are killed by frost during the autumn season. Young winter annual plants live through the winter then flower, set seed and die out the following summer. It is therefore proposed that the small granivorous bird assessment at this tier is not relevant for application to kiwifruit.

[3] https://ag.umass.edu/sites/ag.umass.edu/files/fact-sheets/pdf/weed_life_cycles.pdf

Apart from diet, the dissipation of cyanamide on food items is an important consideration for refinement. The EFSA (2010) assessment has maintained a default DT50 of 10 days on food items. However, cyanamide is not a persistent chemical in the environment. In their conclusion, the US EPA observed that the potential for chronic risks was of greater concern than acute risks, however, available data for cyanamide indicate that this chemical degrades rapidly in the environment. Without prolonged exposure, chronic risks to birds may be considerably reduced, and since there is a geographic and temporal limitation of hydrogen cyanamide use, these factors further reduce the extent of potential exposure (US EPA, 2016).

Given the diet arguments above, the main food item of concern is likely to be ground based insects. There are no data to consider dissipation of cyanamide from insects. It is proposed to apply the soil DT50 in this case as a surrogate, and is considered appropriate for several reasons:

1. EFSA (2009) defaults to a 10 day half-life for residues on food items that includes both plants and arthropods despite active constituents often demonstrating much longer environmental half-lives in other environmental media such as soil, water or sediment;
2. In the case of arthropods, this default value may well overestimate persistence. EFSA (2009) considered the time course of residues as reported in 90 data sets from field trials with the data comprising measured residues of insecticides, fungicides and herbicides on the three strata ground-dwelling, leaf-dwelling and flying insects during intervals of 0 to 7 days after spray application;
3. First inspection of the data revealed that in about 50 % of the cases, highest residues did not occur on the day of application, but up to 7 days later. This is probably due to the uptake of residues by arthropods from contaminated soil and plant surfaces and confirms, in principle, the more complex nature of residue dynamics on arthropod food items as compared to plant food items.
4. In the case of cyanamide, a 7 day delay to peak residues represents more than two soil half-lives.
5. For the ground dwelling arthropods, based on 70 field study results, the DT50 of the suite of pesticides was 3.5 days based on SFO kinetics and 1.6 days based on biphasic (FOMC) kinetics.

If an arthropod DT50 of 1.4 days (cyanamide 80th percentile soil half-life) is used as a surrogate, the 21 d TWA is adjusted from 0.53 (10 day half-life) to 0.01 for application in the chronic assessment. It is also important to apply this half-life to short term exposure given the dietary studies involved continual dosing through the diet for 5 days. A 5 day TWA fraction of 0.39 will be applied to exposure estimated in the acute assessment.

Revised risk outcomes

The following modelling still applies the EFSA generic focal species for early stage application in vine scenarios, but has taken into consideration the proposed refinements to exposure modelling described above.

Table 25: Small insectivorous bird, 50% ground arthropods

Species	Small insectivorous bird			
Body weight (g)	16			
Diet component	Ground arthropods (50%)			
Food intake rate (g/d)	6.6	This is the food intake rate based only on this diet source. The total food will be higher based on consumption of foliar arthropods from other sources, but not applicable to calculating exposure.		
FIR/BW	0.40			
	Short term exposure		Long term exposure	
Residues at time of application (mg/kg)	6.9	90^{th} percentile	3.75	Mean residues
Time weighted average factor	0.39	5 days	0.10	21 days
Estimated theoretical exposure (mg/kg bw/d)	27		3.8	
Toxicity end-point (mg/kg bw/d)	>1042		13.3	
Risk quotient	**<0.03**		**0.28**	

Table 26: Small Omnivorous bird, 50% ground arthropods

Species	Small insectivorous bird			
Body weight (g)	28.5			
Diet component	Ground arthropods (50%)			
Food intake rate (g/d)	9.6	This is the food intake rate based only on this diet source. The total food will be higher based on consumption of other dietary items, but not applicable to calculating exposure.		
FIR/BW	0.34			
	Short term exposure		Long term exposure	
Residues at time of application (mg/kg)	6.9	90^{th} percentile	3.75	Mean residues
Time weighted average factor	0.39	5 days	0.10	21 days
Estimated theoretical exposure (mg/kg bw/d)	23		3.2	
Toxicity end-point (mg/kg bw/d)	>1042		13.3	
Risk quotient	**<0.04**		**0.24**	

Applying this approach indicates the short term risk to birds is acceptable, and this is supported by the field evidence described below. The application rate in the field study described is lower than that used in New Zealand, but the results are useful for reiterating the arguments provided above regarding the over estimation of risk from applying an acute gavage based toxicity result in the risk assessment, and support the additional modelling using the dietary based toxicity value that demonstrated the acute risk could be accepted.

The risk to birds through chronic exposure still has not been fully mitigated. While the German assessor did not consider the field study suitable for estimating a PT value (proportion of time spent foraging in the treated area) for the focal species, this was because birds were not followed for a whole day's period. The use of telemetry data does, however, provide good evidence that birds are not spending their entire time in the treated area. Based on the telemetry findings, birds spent, on average, 21% of their time in the fields of application. If this value is included in the above refined modelling, chronic risk quotients are reduced to 0.05-0.06 which is below the NZ EPA LOC for threatened species and indicates an acceptable risk.

Field evidence

A study was reported in the updated Draft Assessment Report undertaken by Germany (Volume 3 Annex B, part 9, B.9, January 2010) considering exposure and effects on birds in grapevine plantations following application with Dormex (520 g/L cyanamide). The study was conducted in four grapevine plantations in Spain and treated at an application rate of 18 L product/ha. The selected plantations were treated once.

The fate of individual birds trapped within the fields and tagged with radio transmitters were examined by radio telemetry from up to 3 days prior to the application until approximately one week after application. Visible acute effects caused by the application of cyanamide from the time of application up to six hours after application were observed by visual observations. In order to quantify the bird abundance and to detect possibly lethally or sub-lethally affected birds, the study fields were surveyed three times after application on days 0, 2 and 5. Further, carcass searches were implemented within the treated fields including a strip of adjacent habitats of approximately 5 m to gather all birds possibly killed by the test item.

The carcass search efficiency was high (70%). One dead greenfinch was found during the search on Day 0. Pathological investigation stated that the bird was dead for at least 12 h prior to being found. The death was not considered to be treatment related.

For the telemetry surveys, a total of 187 birds was trapped in the nets in all field studies with 65 being tagged. Based on the individual birds that used the study fields at least once after application the percent of "exposed birds" ranged from 55.6% to 100%. Calculation of the proportion of time birds used the study fields was based on the localisation of birds tagged with radio transmitters. Each localisation obtained by means of telemetry was recorded as inside or outside the plantation. These results for the four fields showed the % of fixes inside the treated field ranged from 7.5-30.5% with an overall proportion of time in the field of 21.2% based on all four fields.

In terms of visual observations, 1380 sightings of 28 bird species were recorded. None of the sightings revealed signs of abnormal behaviour or any other signs of intoxication. Birds were observed leaving the study field after being disturbed by the spray tractor during application, but sightings of birds entering the freshly treated field were also recorded. Overall, there was a high bird activity within the treated areas and accordingly a high level of exposure. In all 891 bird sightings recorded for the period of visual observations during application and re-entry time, no signs of intoxication could be detected. In all 489 bird sightings recorded during the 12 surveys over days 0, 2 and 5 on each field study, no signs of intoxication could be detected.

It was concluded that, in spite of the high acute risk identified in the risk assessment, the application of Dormex did not lead to mortality within the exposed natural bird community and the acute risk to birds from the application of Dormex in grapevine plantations in winter was considered to be low.

5 Human Health Risk Assessment

Acceptable Operator Exposure Level (AOEL)

EPA (2020) is relied on for guidance in establishing the AOEL.

The AOEL represents the internal (absorbed) dose available for systemic distribution from any route of exposure and is expressed as an internal level, usually in milligrams per kilogram of body weight per day (mg/kg bw/d).

The AOEL is normally derived by applying an assessment factor to a No Observed Adverse Effect Level (NOAEL) from a toxicological study in which animals were dosed daily for 90 days or longer. This assessment factor is most often 100. If appropriate, it will be corrected for incomplete oral absorption in the study from which the NOAEL is derived. Importantly, however, EPA (2020) allows for the critical NOAEL coming from a study with a shorter dosing period, for example, a developmental study.

This option is applied in the cyanamide assessment as it is related to the work rates for pesticide handler operators using cyanamide in application to kiwifruit.

The work rate, or area to be treated per day, should be based on that proposed by the applicant (EPA, 2020). Advice from industry is that in most cases one operator would not spray more than 10 hectares per day, and no more than 120 hectares per growing season. This equates to 12 full time equivalent days of operation per season and therefore, use of a critical toxicity value based on 90 days continuous dosing is overly conservative.

There are two developmental studies available for (Hydrogen) Cyanamide. The rat study (NOAEL 5 mg/kg bw/d) saw continuous dosing for 11 days during gestation. The second study with rabbits resulted in a similar NOAEL (6 mg/kg bw/d) with dosing for a 14 day period. The consistency between these results with a dosing period corresponding essentially to the full time equivalent number of days an operator would be spraying represents a more realistic exposure period and the NOAEL of 5 mg/kg bw/d will be used to establish the AOEL. There is international precedence for this value and applying it due to a more appropriate exposure regime (refer to US EPA 2014a; 2014b; 2015 and 2016 for discussion on acceptance of this value over the 90 day dog study result). No additional correction for incomplete oral absorption has been applied because cyanamide was shown to be extensively absorbed during oral dosing.

This value is that is also used by EFSA (2010) in the establishment of their acute reference dose (ARfD) and EFSA (2010) applied a level of concern of 0.01 (equivalent to a MOE of 100), which resulted in a final ARfD of 0.05 mg/kg bw/d. The level of concern of 100 is in agreement with the EPA default assessment factor of 100 in establishing an AOEL, so a final value of 0.05 mg/kg bw/d will be applied.

Dermal absorption

When substance specific dermal absorption data are not available, the EPA applies a default value of 6% dermal absorption for the liquid concentrate and 30% for the spray dilution.

In their initial assessment (US EPA, 2014b), a dermal absorption factor of 11% was used, derived from the *in vivo* rat dermal penetration study. In this study, rats were treated with 0.1, 1.0 or 10.0 mg/rat (equivalent of 8, 80 or 800 $\mu g/cm^2$). The dermal absorption increased with increasing dose and 24 h absorption was 1.8, 2.8 and 11%, respectively. Following comments back on their initial decision, the US EPA checked the magnitude of the expected occupational exposure and revised the dermal absorption factor of 2.84% from the *in vivo* rat dermal penetration study resulting from application of 80 $\mu g/cm^2$ (US EPA, 2014c). This factor will be applied in the following modelling due to the demonstrated lower level of occupational exposure in New Zealand.

New Zealand EPA Occupational Handler Exposure Model

The following inputs are established for the exposure modelling:

Table 27: Input values for cyanamide occupational exposure modelling

Exposure scenario	Estimated operator exposure (mg/kg bw/day)
Application rate (Highest)	25 kg ac/ha
AOEL	0.05 mg/kg bw/d
Dermal absorption	2.84% (concentrate and dilute spray

Table 28: Output of operator mixing, loading and application exposure assessment for cyanamide in commercial end uses – Kiwifruit (Airblast application)

Exposure scenario	Estimated operator exposure (mg/kg bw/day)	Risk Quotient
No PPE during mixing, loading and application	1.476	29.53
Gloves only during mixing and loading	1.257	25.14
Gloves only during application	1.412	28.25
Full PPE during mixing, loading and application (excluding respirator)	0.153	3.05
Full PPE during mixing, loading and application (including FP1, P1 and similar respirator achieving 90 % inhalation exposure reduction)	0.093	1.86

Without PPE the risk quotients are very high and using the EPA approach with the EFSA (2010) end-points, airblast applicator scenarios do not reach an acceptable risk quotient. Where full PPE is modelled, risk quotients exceed the EPA level of concern but the exceedance is not high.

PERAMNZ can spilt the dermal and exposure route for the risk assessment to better indicate where the main risk is coming from and this is shown in the following table:

Table 29: Output of operator mixing, loading and application exposure assessment for cyanamide in commercial end uses – Kiwifruit (Airblast application). Individual exposure routes

Exposure scenario	Estimated operator exposure (mg/kg bw/d)		Risk quotient	
	Dermal	Inhalation	Dermal	Inhalation
No PPE during mixing, loading and application	1.41	0.066	28.2	1.33
Gloves only during mixing and loading	1.19	0.066	23.8	1.33
Gloves only during application	1.35	0.066	26.9	1.33
Full PPE during mixing, loading and application (excluding respirator)	0.086	0.066	1.72	1.33
Full PPE during mixing, loading and application (including FP1, P1 and similar respirator achieving 90 % inhalation exposure reduction)	0.086	0.0066	1.72	0.13

This analysis shows that dermal exposure is the main route for operators. Thus, measures taken to reduce dermal exposure have the greatest impact at reducing risk quotients.

The risk quotients with full PPE, while exceeding the EPA levels of concern, remain low (<2). EPA (2020) allows for consideration of other options to model occupational exposure if the risk quotient exceeds 1 using their approach.

US EPA Occupational Handler Exposure Model

The most recent suite of exposure values is available from the US EPA with their Microsoft Excel spreadsheet for the US EPA Occupational Pesticide Handler Exposure Calculator (version date: March 2020) are available at https://www.epa.gov/sites/production/files/2020-03/opp-hed-occupational-handler-exposure-march-2020.xlsx. The exposure values are derived from a number of sources including the Pesticide Handler Exposure Database (PHED) and the Agricultural Handler Exposure Task Force (AHETF).

The values and processes from this spreadsheet calculator have been developed into a software tool (PHRAMA[4]). This software has been developed to comply with APVMA requirements for the various aspects of the OH&S. For this modelling, the default NZ EPA input values for body weight (70 kg) and work rate (10 ha/d with airblast application) are incorporated.

Please note, the outcomes in the following modelling are discussed in terms of an acceptable margin of exposure as opposed to a risk quotient. Based on the toxicity end-point of 5 mg/kg bw/d, the AOEL is determined by applying an assessment factor of 100 (AOEL = 0.05 mg/kg bw/d). The acceptable margin of exposure in the following modelling is 100, so the results are directly comparable in that the allowable dose needs to be 100 times less than the toxicity end-point, which will equate to the AOEL.

Mixing/Loading

Table 30: Dose (mg/kg/d) in mixing/loading operations, application rate 25 kg ac/ha; work rate 10 ha/day.

	DERMAL EXPOSURE ROUTE				INHALATION ROUTE	
Control	Single layer, no gloves	Single layer, gloves	Double layer, gloves	Engineering control	No Respirator	PF10
Exposure (µg/kg)	485	82.8	64.1	18.94	0.483	0.0483
Dose (mg/kg bw/d)	0.04915	0.00840	0.00650	0.00192	0.00172	0.000173
Margin of exposure	**102**	**595**	**769**	**2603**	**2900**	**28986**

Table 31: Margin of exposure from combined dermal and inhalation routes, application rate 25 kg ac/ha; work rate 10 ha/day.

Control, dermal Control, Inhalation	Single layer, no gloves	Single layer, gloves	Double layer, gloves	Engineering control
No respirator	**98**	494	608	1372
Respirator, PF10	101	583	749	2388
Respirator, PF50	102	593	765	2557

Chemical resistant gloves are required during mixing/loading operations based on the combined margin of exposure from both dermal and inhalation exposure routes.

Application

Table 32: Dermal Dose (mg/kg/d) in application operations, application rate 25 kg ac/ha; work rate 10 ha/day. Airblast application

	DERMAL EXPOSURE ROUTE					
Control	Single layer, no gloves	Single layer, gloves	Double layer, gloves	Single layer, gloves and hat	Double layer, gloves and hat	Engineering control
Exposure (µg/kg)	3899	3503	3260	474	311	32.2

[4] **P**esticide **H**ealth **R**isk **A**ssessment **M**odel for **A**ustralia. © Australian Environment Agency Pty Ltd 2019.

Dose (mg/kg bw/d)	0.395	0.355	0.33	0.048	0.31	0.0033
Margin of exposure	**13**	**14**	**15**	**104**	**159**	**1,535**

Table 33: Inhalation Dose (mg/kg/d) in application operations, application rate 25 kg ac/ha; work rate 10 ha/day. Airblast application

	INHALATION EXPOSURE ROUTE			
Control	No respirator	Respirator, PF10	Respirator, PF50	Engineering control
Exposure (µg/kg)	10.4	1.04	0.21	0.15
Dose (mg/kg bw/d)	0.037	0.004	0.0074	0.00054
Margin of exposure	**135**	**1,351**	**6,751**	**9,355**

Table 34: Margin of exposure from combined dermal and inhalation routes, application rate 25 kg ac/ha; work rate 10 ha/day. Airblast application.

Control, dermal	Single layer, no gloves	Single layer, gloves	Double layer, gloves	Single layer, gloves and hat	Double layer, gloves and hat	Engineering control
Control, Inhalation						
No respirator	**12**	**13**	**14**	**59**	**73**	**124**
Respirator, PF10	**13**	**14**	**15**	**97**	**142**	**719**
Respirator, PF50	**13**	**14**	**15**	**103**	**155**	**1,251**

For applicators, acceptable exposure is calculated where application is conducted within an enclosed cab (engineering control). If application is not conducted in an enclosed cab, applicators would be required to wear coveralls over clothing with chemical resistant gloves and hat; and a respirator (PF10 or better).

New Zealand EPA Bystander Exposure Model

The methodology for the bystander assessment is as described in EPA (2020).

Exposure is estimated using the equations from the European Food Safety Authority (EFSA) which account for dermal exposure, hand-to-mouth exposure and object-to-mouth exposure (EFSA, 2014). In addition, incidental ingestion of soil is taken into account using a modified exposure equation from the United States Environmental Protection Agency (USEPA).

Dermal absorption is also factored into the dermal exposure assessment. In this case the dermal absorption value used is the value for the diluted spray. Dermal absorption values have been discussed above.

The Agdrift model has been applied as per NZ EPA standard curves to calculate the required downwind buffer zone to protect bystanders due to spray drift. In addition, the deposition curve developed for kiwifruit based on measured data using AI nozzles and driftstop (NU0017) has been modelled (see Table 14 for deposition curve).

The equation applied by NZ EPA to calculate exposure is:

$$PEC_{single} = SE(d) + SE(h) + SE(o) + ADOD \quad \text{(equation 1)}$$

where:

PEC = predicted environmental concentration following a single application
SE(d) = systemic exposure via the dermal route
SE(h) = systemic exposure via the hand-to-mouth route
SE(o) = systemic exposure via mouthing activity
ADOD = soil ingestion oral dose on day of application.

The four elements that make up the model in Equation 1 are calculated using the following EFSA and USEPA equations:

$$SE(d) = \frac{(AR)(DF)(TTR)(TC)(H)(DA)}{BW} \quad \text{(equation 2)}$$

$$SE(h) = \frac{(AR)(DF)(TTR)(SE)(SE)(Freq)(H)(OA}{BW} \quad \text{(equation 3)}$$

$$SE(o) = \frac{(AR)(DF)(TTR)(IgRg)(OA)}{BW} \quad \text{(equation 4)}$$

$$ADOD = \frac{(AR)(DF)(F)(IgRs)(SDF)(OA)}{BW} \quad \text{(equation 5)}$$

where:

AR = field application rate
BW = body weight
DA = percent dermal absorption
DF = spray drift value
F = fraction or residue retained on uppermost 1 cm of soil (this is an adjustment from surface area to volume)
Freq = frequency of hand to mouth events H = exposure duration for a typical day
IgRg = ingestion rate for mouthing grass/day
IgRs = ingestion rate of soil
OA = oral absorption (fraction)
SA = surface area of the hands
SDF = soil density factor = volume of soil (cm^3) per milligram of soil
SE = saliva extraction factor
TC = transfer coefficient
TTR = turf transferable residues.

The NZ EPA default values as required for the above equations are taken from EPA (2020).

Table 35: Matrix of buffer zones using NZ EPA methodology for bystander assessments based on differences in spray drift scenarios; AOEL = 0.05 mg/kg bw/d; Dermal absorption = 2.84%

Spray drift scenario	Vineyard	Kiwifruit[1]
Dermal absorption	2.84%	2.84%
SE(d)	1.60	1.32
SE(h)	2.06	1.69
SE(o)	1.083	0.892
ADOD	0.0145	0.0119
Fdep	0.1367	0.1367
Exposure (µg/kg bw/d)	4.76	3.91
RQ	0.10	0.08
Buffer zone (m)	**8**	**8**

1) Based on deposition profile described in Table 14

The bystander buffer zone of 8 m is based on the EPA assessment method commencing from 8 m downwind.

6 Conclusions and recommendations

This assessment has been undertaken to NZ EPA methodology to address concerns relating to environment and human health raised in the grounds for reassessment of cyanamide. The assessment has relied on assessments from international regulators, specifically, the European Food Safety Authority (EFSA) and the United States Environment Protection Agency (US EPA).

Cyanamide is not persistent in the environment. However, it is toxic to aquatic organisms and is highly mobile. Assessment of aquatic risk through exposure from spray drift or runoff has resulted in controls being recommended in the form of downwind buffer zones (spray drift – 6 m) or downslope buffer zones (runoff – 14 m). The spray drift buffer zone was determined based on measured data (90th percent) for application to dormant kiwifruit where airblast equipment used air induction (AI nozzles) and was mixed with the adjuvant NU0017. The downslope buffer zones were refined applying knowledge of regional specific slope data in horticultural areas where kiwifruit is grown. Using the EPA screening approach for groundwater assessment, the exposure to groundwater was shown to be acceptable.

The standard low tier approach to birds risk assessment highlighted a potential acute and chronic risk. The risk assessment was refined through addressing both exposure modelling and considering other lines of evidence. Food items not likely to be found in avian diets during winter given the timing of application (vine foliage; weed seeds) were removed from the exposure calculations. The dietary toxicity value was applied rather than the acute oral toxicity value obtained by gavage dosing and not representing reality. The acute risk was demonstrated to be acceptable and is supported by field study results. The chronic risk was not fully mitigated through updated modelling. However, considering additional evidence from the field study where it was shown birds are not expected to spend much more than 20% of their time in the treated fields, the risk quotients were acceptable for threatened and non-threatened species.

The human health assessment considered occupational handler exposure through mixing/loading and application activities, and bystander risk. The methodology and refinements followed the guidance from EPA (2020). Risk quotients for handlers during mixing/loading/application operations following the EPA model showed an unacceptable risk with full PPE and respirator. However, the risk quotients with full PPE were <2, so a refined modelling approach was adopted using the latest dermal and inhalation exposure values applied by the US EPA in their 2020 calculator. Using this modelling, mixing/loading operations were acceptable provided chemical resistant gloves were worn. However, applicators are required to either operate within an enclosed cab, or wear coveralls, a washable hat, chemical resistant gloves and a respirator. Bystander risk was shown to be acceptable with a downwind buffer zone of 8.

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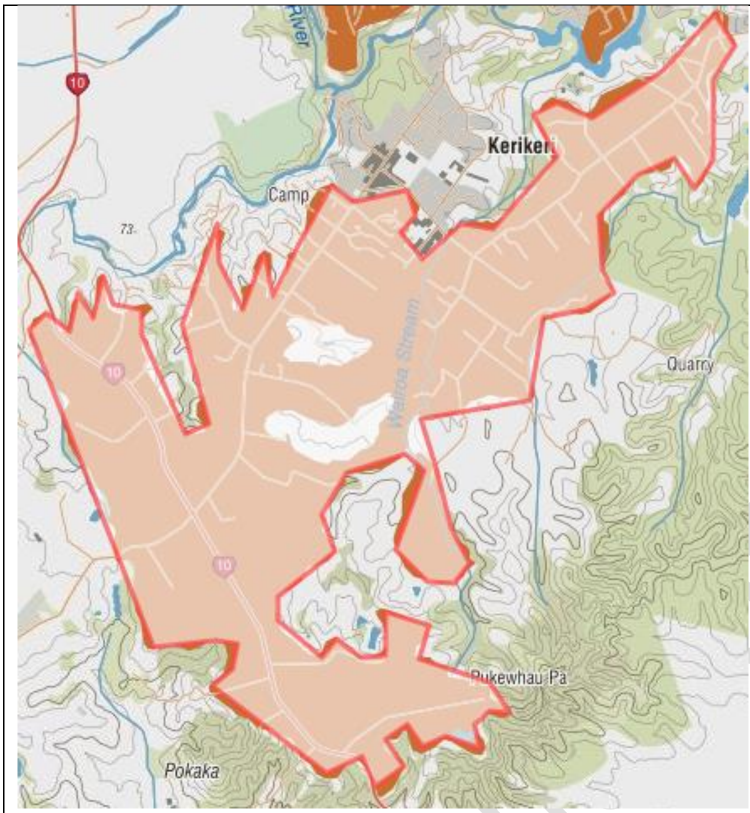
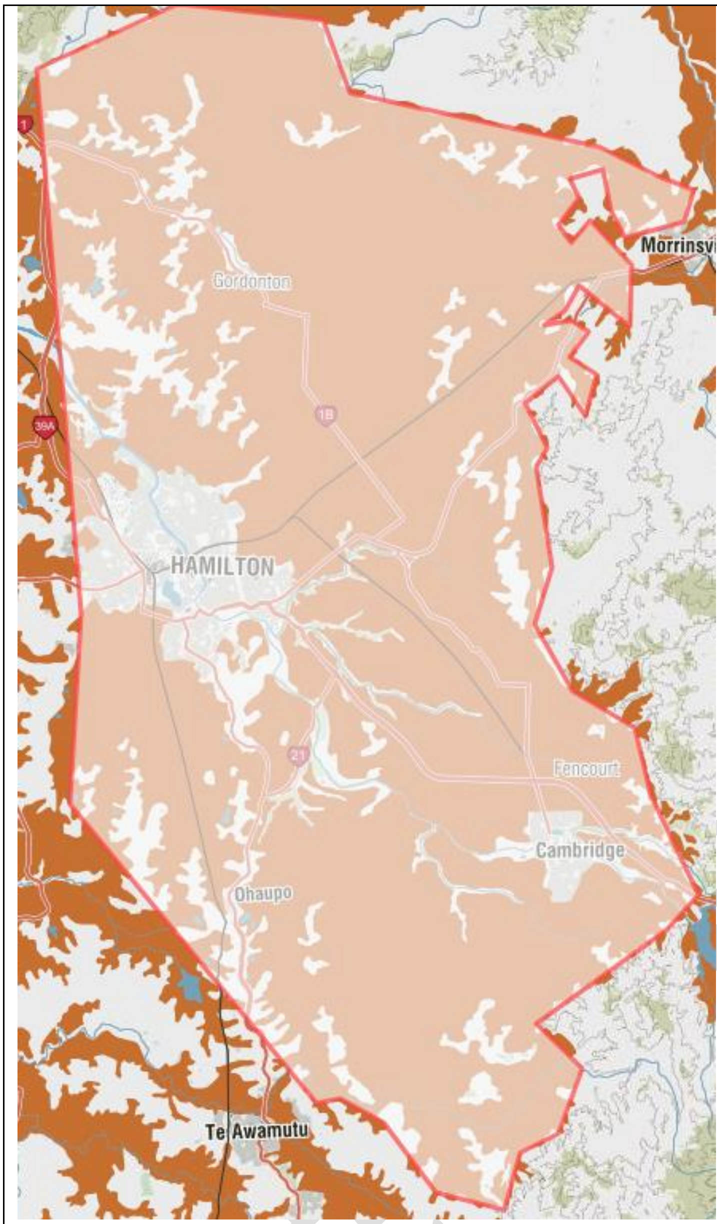
APPENDIX 1 – Slopes Analysis in Kiwifruit Growing Regions

In order to consider the expected slopes within the growing areas of these regions additional information has been through Manaaki Whenua – Landcare Research, specifically applying map layers for intensive horticulture and steepness of slope[5].

	**Northland (Area around Kerikeri)** Area mapped – 1261 ha Area to horticulture – 91%, 1142 0-3º slope – 71% 4-7º slope – 31%

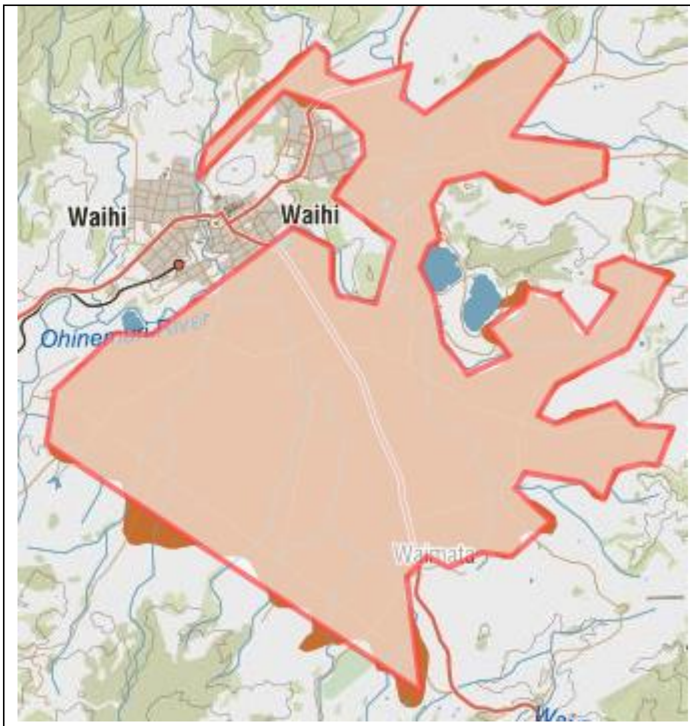
[5] https://ourenvironment.scinfo.org.nz/maps-and-tools/app/

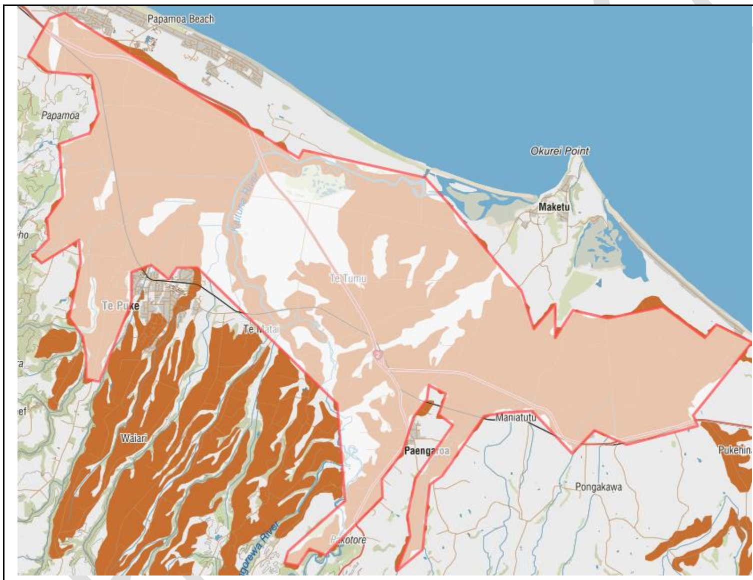


Waikato (Cambridge)

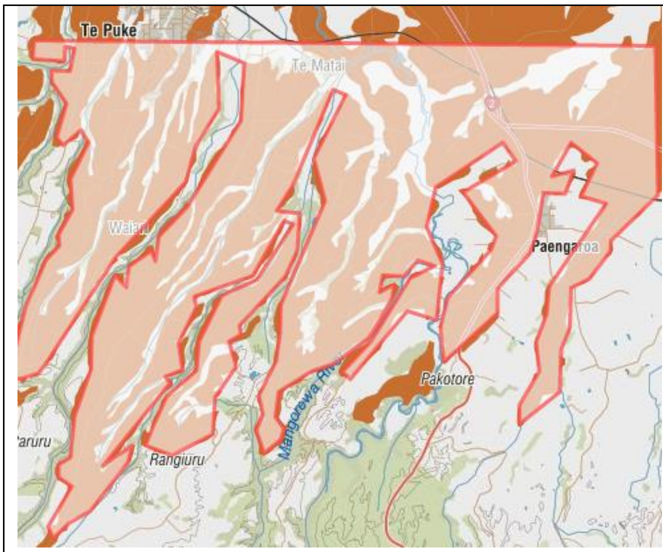
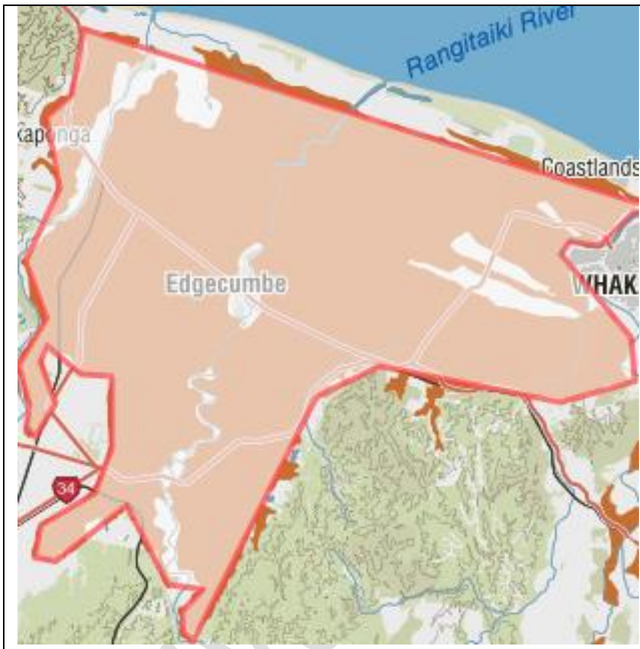
Area mapped – 101959 ha
Area to horticulture – 80%, 81391

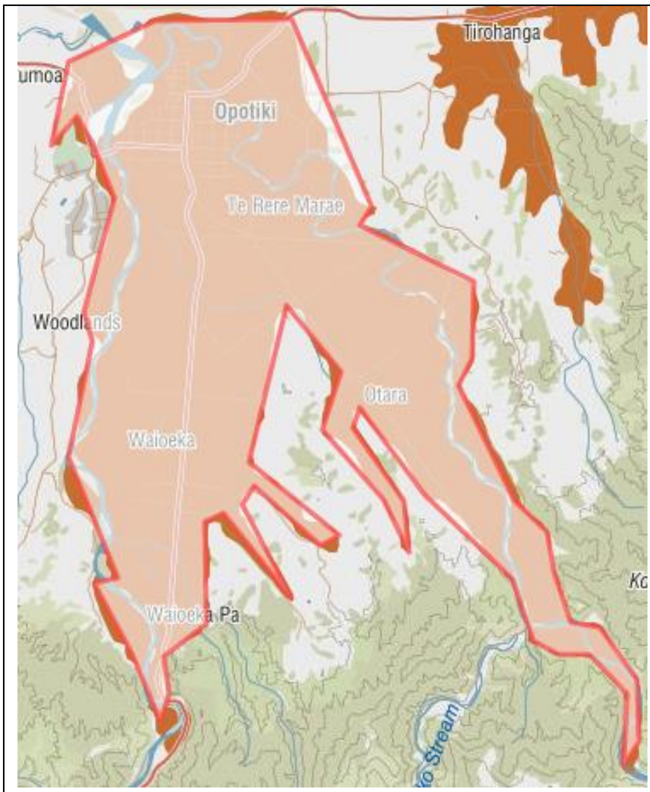
0-3° slope – 94%
4-7° slope – 4.4%

	**Bay of Plenty – Area around Waihi** Area mapped – 3432 ha 0-3º slope – 94% 4-7º slope – 7.4%

	**Bay of Plenty – Area around Te Puke** Area mapped – 13646 ha 0-3º slope – 100%

Due to the scale, the “fingers” are difficult to map. The following shows the broad area:

	Area mapped – 7346 ha Area to horticulture 78% (5748 ha) 0-3º slope – 78% 4-7º 19%%
	**Bay of Plenty – Area around Edgecumbe** Area mapped – 20796 ha 0-3º slope – 100%

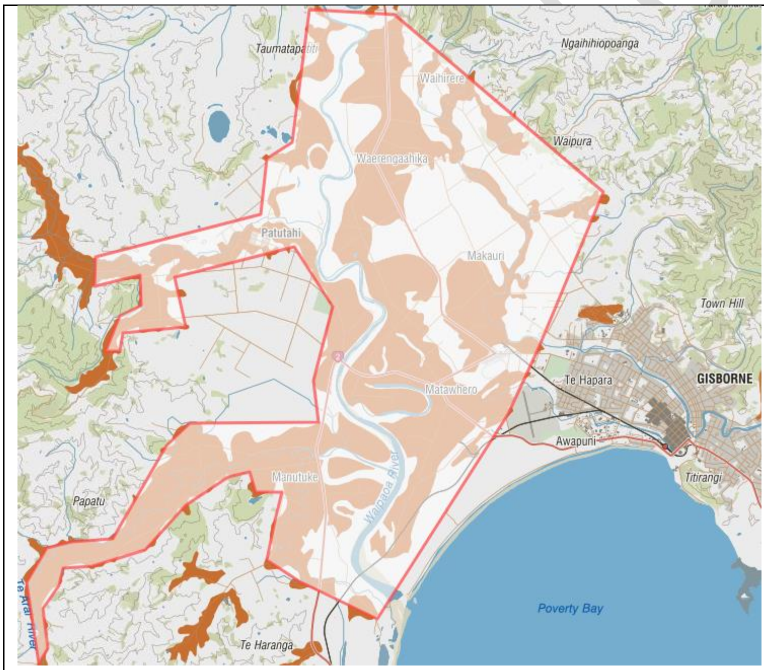


Bay of Plenty – Area around Opotiki

Area mapped – 4334 ha

0-3º slope – 93%

4-7º 7.5%%



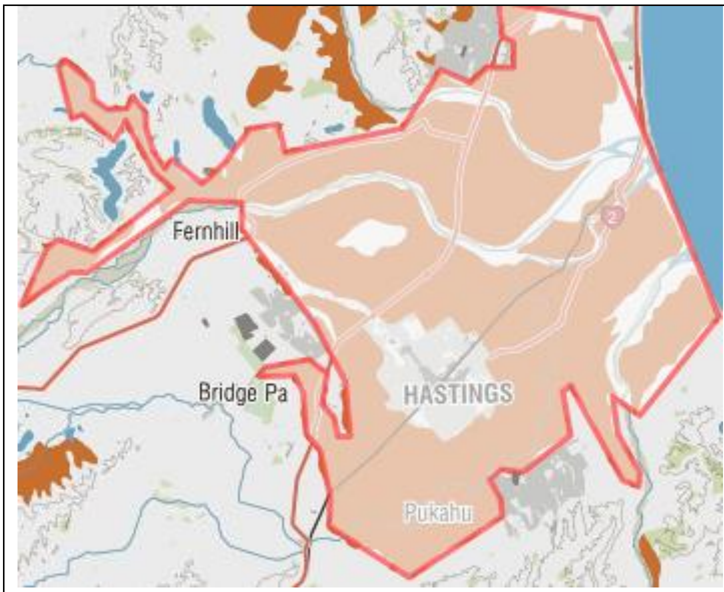
Gisborne

Area mapped – 11226 ha

Area to horticulture – 51% (5738 ha)

0-3º slope – 96%

4-7º 3.4%%



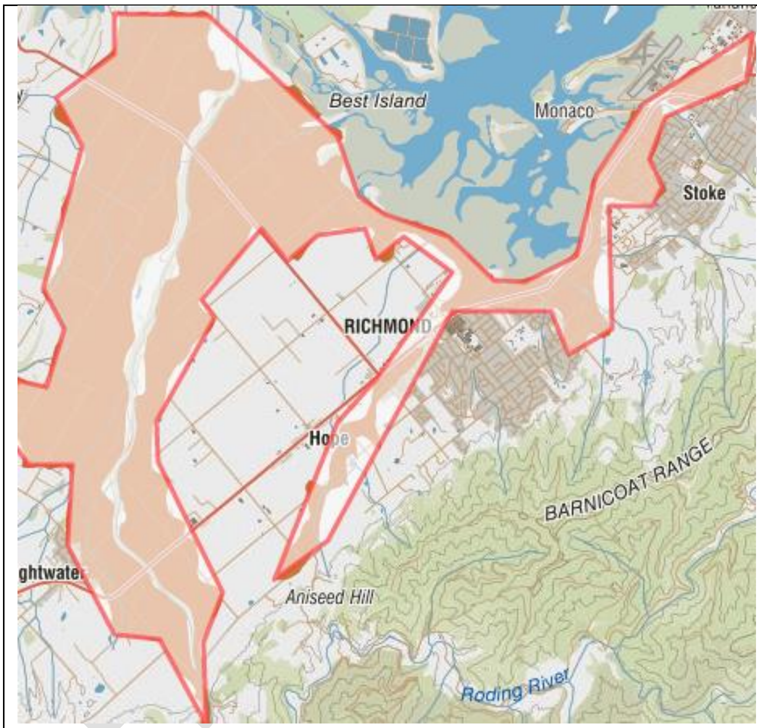
Hawkes Bay

Area mapped – 20587 ha

Area to horticulture – 77% (15770 ha)

0-3º slope – 98.2%

4-7º 1.8%



Nelson

Area mapped – 4205 ha

Area to horticulture – 81% (3397 ha)

0-3º slope – 98.5%

4-7º 1.4%