Environmental Protection Authority
Te Mana Rauhī Taiao

Responses to Zespri's questions on the EPA's hydrogen cyanamide reassessment application

Background

Zespri International sent a letter dated 14 October 2021 to the EPA with a list of questions on the hydrogen cyanamide reassessment. The questions related mainly to the EPA's risk assessments, proposals, and definitions of technical terms used in the application documents. To ensure that all potential submitters have equal access to information, the full list of questions and answers is being published.

1. What is the definition of non-target and threatened plants and water body? This is in relation to the proposed buffer zones and modelling/risk assessments.

Non-target plants

In the risk assessment, the term "non-target plants" encompasses all "non-crop vascular plants growing outside of the treated area".

The land "outside of the treated area" is typically referred to as "off-field" and is defined as the area of non-treated land surrounding the site that has been treated.

This off-field area is considered to begin at the edge-of-field (ie. directly adjacent to the treated area) and extends to the maximum distance that the substance can travel by spray drift. The boundary of the off-field area considered is thus defined by the spray drift curves used. The BBA spray drift curves are the standard spray drift curves used in the non-target plant risk assessment. These spray drift curves cover a distance of up to 250 m downwind of the treated area. The off-field area is thus considered to include non-target plants growing at distances of up to 250 m downwind of the treatment site.

Threatened plants

Section 3.3.4 of the EPA's Risk Assessment Methodology[1] defines threatened species as follows:

> "For the purposes of New Zealand risk assessments, the threatened species are those included in the following categories of the New Zealand Threat Classification System (Department of Conservation, 2017):
>
> - 'Threatened' (nationally critical, nationally endangered, nationally vulnerable)
> - 'At risk' (declining, recovering, relict, naturally uncommon)."

Further details of when and how to consider threatened species are also included in Appendix C of the EPA's Risk Assessment Methodology.

Water body

Where this term has been used in previous approvals for hazardous substances or in guidance documents, it is generally defined as follows:

Water body	Includes all natural and modified/artificial water courses such as reservoirs, irrigation canals, water-supply races, canals for the supply of water for electricity generation or farm drainage, ditches, streams, rivers, ponds and lakes. For clarity, it excludes fully covered pipes, tanks or other enclosed structures, puddles or groundwater.
Watercourse or Waterway	Includes every river, stream, passage, and channel on or under the ground, whether natural or not, through which water flows, whether continuously or intermittently.

2. What real-world/incident information do the EPA hold on the risk to non-target plants? We are aware some fruit-bearing trees have been adversely affected from off-target exposure but are not aware of there being phytotoxicity issues in general. Yes, the modelling says risks are above LOC, but what reports do the EPA have of there being risks other than to fruit-bearing trees? How about grass?

The non-target plant risk modelling uses laboratory data from standard seedling emergence and vegetative vigour tests carried out with plant species including corn, soybean, carrot, cabbage, lettuce, tomato, cucumber, onion, oat and perennial ryegrass. As noted in the science memo, these studies are summarised in the EU DAR (EC 2006).

[1] https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Risk-Assessment-methodology/Risk-Assessment-Methodology-for-Hazardous-Substances-How-to-assess-the-risk-cost-and-benefit-of-new-hazardous-substances-for-use-in-New-Zealand-v2.docx

The science memo also comments on the earlier registration of hydrogen cyanamide as a herbicide:

> "*The EU DAR (EC 2006) mentions that hydrogen cyanamide had been registered as a herbicide for control of dicotyledonous weeds in onions, leeks and chives in Germany*"

In terms of incident information on risks to non-target plants, the EPA received a limited amount of "anecdotal" evidence during the call for information. Information received by the EPA included direct reports from individuals, as well as indirect reports from complaints information held by the Bay of Plenty Regional Council. This is summarised in the following extract of the science memo:

> *"During the call for information the EPA has received reports of damage of trees (eg citrus, grass, shelterbelts) due to the use of hydrogen cyanamide. Based on the visual effects observed in the toxicity studies, referenced in the DAR, these effects are considered possibly related to the drift of hydrogen cyanamide (at 20 kg ai/ha the highest phytotoxicity rating was 75% of control in a tier 1 vegetative vigour study)."*

Product labels submitted during the call for information also highlight susceptibility of *Casurina* spp., lemons, tamarillos and gum trees to hydrogen cyanamide.

3. What assumptions does the runoff risk assessment make, and the modelling account for, for interception by grass and other vegetation before runoff would enter waterways?

The runoff modelling takes into account the use pattern of the substance (by application rate and number of applications) and the two key substance-specific environmental fate parameters, which are the degradation rate of the substance in soil (DT_{50} or half-life) and mobility of the substance in soil (K_D or partition coefficient), which is the key retention mechanism reducing pesticide mobility in the soil environment.

Regarding runoff processes, the runoff model assumes that a rainfall event occurs 3 days after substance application. On this day, 10% of the pesticide applied to the treated field is assumed to run off the treated field, using a worst-case slope of 12.5%, into an adjacent waterbody. The concentration of the substance that runs off into the waterbody is thus calculated based on these runoff process assumptions and taking into account the use pattern and substance-specific input parameters mentioned above.

There are two ways the concentration of the substance in the waterbody can be refined in the runoff model thereafter: crop interception and the slope.

Crop interception decreases the amount of pesticide that reaches the soil surface and thus ultimately enters the surface water body via runoff/drainage. Following our standard

approach, only interception by the crop canopy itself is considered (ie. the kiwifruit vines or apple orchards in this case).

Additional interception by grass and other vegetation that may be present in between the rows of tall perennial/permanent crops such as kiwifruit vines is not considered in the standard modelling approach (ie. the soil beneath tall perennial/permanent crops is assumed to be bare). Based on data from Europe and anecdotal evidence, kiwifruit vines and apple orchards do usually have a degree of crop cover (ie. grass) between the rows (Beulke *et al*. 2015). It is therefore relevant to consider interception by grass and/or additional vegetation between tall permanent/perennial crops, which would reduce the amount of substance available for runoff. Other canopy processes, for example subsequent potential wash-off of the substance from the crop that would increase the amount of substance available for runoff, are not considered in the model either, however.

The slope value was refined using New Zealand specific spatial analysis (GIS) as described in detail in Appendix J of the science memo.

4. In terms of the data in table 5 of the application report, what is meant by the phrase in areas where hydrogen cyanamide is used?

This phrase is a simply quoting the information received from WorkSafe, and is clarified in the sentence following that phrase in the application report:

> "Most of the site visits were kiwifruit orchards, across regions including Nelson/Tasman, Northland, Bay of Plenty, Poverty Bay, Hawkes Bay, Te Puke, and Ōpōtiki."

5. How is the EPA defining airblast spraying?

Airblast spraying refers to the method of application or equipment by which certain crops are typically treated eg. fruit crops. In the context of the science memo, the term airblast spraying relates to the selection of appropriate application scenarios for our modelling. For the operator exposure, this corresponds to the relevant scenarios for applications of agrichemicals to orchards' foliage (as opposed to boom applications). For areas for which spray drift is relevant (bystanders, aquatic risk assessment, non-target plant risk assessment), this corresponds to the relevant APVMA & BBA spray drift curves used in our modelling, the airblast vineyard scenario being considered the closest match to a kiwifruit crop.

6. Have AI nozzles and drift reducing adjuvants been accounted for in the drift modelling? If so, how?

No, we have only considered the standard APVMA drift curves. Refer to Appendix M for further details as to why we did not use the specific spray drift curves proposed by NZKGI:

“Spray drift

NZKGI’s consultant argues that the EPA staff should use the spray drift curve generated during spray drift trials by NZKGI. The EPA acknowledges that specific spray drift curves can increase the certainty of the risk assessment and appropriateness of associated controls. The EPA has requested the full study reports of the spray drift trials to evaluate if the results can be used for further refinement. The full report was not provided to the EPA.”

As noted in Box 5 in the Application Report, submitters are encouraged to provide crop-specific spray drift curves with full supporting data and/or refined risk assessments incorporating this information.

7. Has shelter been accounted for in the modelling? If so, how? What consideration was given/is being given to shelter as a control?

“Shelter” (off-field vegetation sheltering) is relevant for the parts of the quantitative environmental risk assessment where the “off-field” situation is considered. The off-field situation is relevant for the soil-dwelling organism, non-target plant and non-target arthropod risk assessments where risks are assessed both in-field and off-field.

The off-field risk results only from spray drift away from the treated site. It is considered that off-field vegetation is likely to be present and assuming bare soil is overly conservative. As such, as a reasonable conservative approach, an off-field vegetation sheltering value of 40% is applied. This value represents the interception by developing grass (BBCH 10-19). Where the assessment is not quantitative, off-field vegetation sheltering was considered qualitatively.

8. The human health risk assessment separates out mixing and loading from application itself when considering the engineering control refinements – use of a closed cab and enclosed mixing system. Could the EPA please do this for the risk assessment in table 29 of the science memo - i.e. the risk modelling involving certain levels of PPE?

An expanded table is provided in Appendix A to this document which reproduces Table 29 of the science memo with additional columns with the results for the estimated internal exposure and RQs for mixing and loading and application separately for each level of PPE.

9. The science memo indicates that closed cab application results in low risks that are still above the acceptable level of exposure. Could you please clarify how this exposure is expected to occur? I.e., is it exposure through the cab filters? Through leaking seals? Walking spills of concentrate or dried product into the cab and being exposed to that? Is it dermal, oral, inhalation or a combination of the three?

The modelling including closed cab application is all based on the scenarios and approach laid out by the US EPA. The EPA assumes that some leakage of the cab may result in some inhalation and dermal exposure even when an enclosed cab with a supplied air system is used. Also, some exposure may occur when the operator gets out of the cab after completion of the work and that would be more likely to be a dermal exposure.

10. The EPA risk methodology says that when modelling risks to birds, either an RQ or TER will be calculated, and that if a TER approach is used this will be converted into RQs to enable comparison with other modelling. This does not appear to be included in the science memo or other appendices. Could the EPA please report the RQs for this risk assessment?

The model used for the bird risk assessment only generates TER values and does not directly generate RQ values. Therefore, generating and reporting the RQ values involves performing some additional calculations.

For efficiency, we have calculated the additional RQ values only for the highest tier of modelling using refined values and at the higher application rates, since a restriction to the lower application rates is not currently proposed.

The expanded versions of Tables 70, 72, 73, and 76 (acute dietary risk assessments) and Table 68 (reproductive risk assessment with an additional column for the calculated RQ values are included in Appendix B to this document).

The calculated RQ values for the bird risk assessments may need to be considered relative to the levels of concern detailed in Table 9 of the EPA's Risk Assessment Methodology in order to perform any comparison with other risk modelling. An excerpt of this table is provided below:

Table 9 Levels of concern (extract from EPA's Risk Assessment Methodology)

Receptor	Acute or chronic exposure?	RQ at LOC (normal)	RQ at LOC (threatened species)
Terrestrial vertebrates (birds)	Acute	0.1	0.05
Terrestrial vertebrates (birds)	Chronic	0.2	0.1

11. There are inconsistencies between how risks/benefits are described in the specific modelling/risk assessment reports, and how they are described in the summary report. Are the proposed controls and the proposal to phase out hydrogen cyanamide based on how risks are described in the summary report or the content of the individual assessments?

The proposed controls are based on those risks and mitigation measures identified in the human health and environmental risk assessments presented in the science memo. The effect of the proposed controls to manage the identified risks, and the residual risks once those controls are in place, are shown in Appendix F – Analysis of risks and practical control measures. The overall proposal for a phase out of hydrogen cyanamide use is based on a weighing up of the residual risks once the proposed controls are in place against the benefits.

Appendix A: Expanded version of Table 29 for response to Question 8

Table 29: Operator exposure for Kiwifruit at top application rate (25 kg/ha)

Exposure Scenario	Standard modelling application and M/L		Mixing and loading (M/L) only		Application only	
	Estimated operator exposure (mg/kg bw/d)	Risk Quotient	Estimated operator exposure (mg/kg bw/d)	Risk Quotient	Estimated operator exposure (mg/kg bw/d)	Risk Quotient
Airblast– maximum rate for kiwifruit (25 kg/ha)						
No personal protective equipment (PPE) during mixing, loading and application	4.6600	466.000	**1.2279**	**122.786**	**3.4321**	**343.214**
Gloves only during mixing and loading	3.5569	355.686	**0.1247**	**12.471**	**3.4321**	**343.214**
Gloves only during application	4.4755	447.550	**1.2279**	**122.786**	**3.2476**	**324.764**
Full PPE during mixing, loading and application (excluding respirator)	0.3676	36.764	**0.1247**	**12.471**	**0.2429**	**24.293**
Full PPE during mixing, loading and application (including FP1, P1 and similar respirator achieving 75 % inhalation exposure reduction)	0.3143	31.431	**0.1231**	**12.311**	**0.1912**	**19.120**
Full PPE during mixing, loading and application (including FP2, P2 and similar respirator achieving 90 % inhalation exposure reduction)	0.3043	30.434	**0.1228**	**12.279**	**0.1816**	**18.156**

In question 8, Zespri asked for the separate risk assessment results for application and mixing/loading in relation to the standard modelling in Table 29.

The original table 29 for both mixing and loading (M/L) and application is reproduced above with the corresponding values for M/L only and application only listed alongside in the same table and highlighted in bold/darker shading.

The results are shown to be correct since if the RQ values for separate M/L and application columns are added together at each row it gives the value for the combined RQ as in the column on the left (and in Table 29) after rounding.

The first row with no PPE is already reproduced in the science memo in Tables 35 and 36 as these values without PPE were used as the starting point for the adjustment to account for possible engineering controls.

Appendix B: Expanded version of Tables 70, 72, 73, 76, and 68 for response to Question 10

The Tables below each contain an additional column with the calculated RQ values for each scenario.

Table 70: TER values for acute dietary risk assessment updated endpoint Kiwifruit (High Rate)

Crops & BBCH class	Generic focal species[1]	Toxicity endpoint value (mg/kg bw/d)*	TER ratio	RQ values	Conclusion
Application rate 25 kg ai/ha – single application					
Orchard BBCH 10-19[1]	Small granivorous bird "finch" Small seeds 100% seeds	>435	>0.8	<1.3	**Potentially above LOC for non-threatened and threatened species** **3.4 – 14x above LOC for non-threatened species** **6.9 – 29x above LOC for threatened species**
	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates		>2.9	<0.3	
Bare soil BBCH <10[2]	Small granivorous bird "finch" Small seeds 100% weed seeds		>0.7	<1.4	
	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates		>1.6	<0.6	
	Small omnivorous bird "lark" Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods		>1.0	<1.0	

[1] Orchard scenario (BBCH 10-19) used as surrogate for kiwifruit and apples since hydrogen cyanamide is applied prior to bud break (ie up to BBCH 09), however no specific scenario is available

[2] Bare soil scenario used as surrogate for applications to kiwifruit and apples

Table 72: TER values for acute dietary risk assessment updated endpoint and uncontaminated seeds Apple (High Rate)

Crops & BBCH class	Generic focal species[1]	Toxicity endpoint value (mg/kg bw/d)*	TER ratio	RQ values	Conclusion
Application rate 25 kg/ha – single application					
Orchard BBCH 10-19[1]	**Small granivorous bird "finch" Small seeds 100% seeds**	>435	Not calculated no exposure		Risk below the level of concern for non-threatened and threatened species.
	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates[3]		>2.9[3]	<0.3[3]	**Potentially above LOC for non-threatened and threatened species[3]** **3.4x above LOC for non-threatened species** **6.9x above LOC for threatened species**
Bare soil BBCH <10[2]	**Small granivorous bird "finch" Small seeds 100% weed seeds**		Not calculated no exposure		Risk below the level of concern for non-threatened and threatened species.
	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates[3]		>1.6[3]	<0.6[3]	**Potentially above LOC for non-threatened and threatened species[3]** **6.3x above LOC for non-threatened species** **12.5x above LOC for threatened species**
	Small omnivorous bird "lark" Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods		**>7.3** **~~>10.8~~** [*error in science memo*]	<0.13	Below LOC for non-threatened species **Potentially above LOC for threatened species** **0.9x below LOC for non-threatened species** **1.9x above LOC for threatened species**

[1] Orchard scenario (BBCH 10-19) used as surrogate for kiwifruit and apples since hydrogen cyanamide is applied prior to bud break (ie up to BBCH 09), however no specific scenario is available

[2] Bare soil scenario used as surrogate for applications to kiwifruit and apples.

[3] Values in grey are included but no residue data was updated (since seeds are not included in these scenarios) and risks are the same as in the previous table

Table 73: TER values for acute dietary risk assessment updated endpoint and uncontaminated seeds Kiwifruit (High Rate)

Crops & BBCH class	Generic focal species[1]	Toxicity endpoint value (mg/kg bw/d)*	TER ratio	RQ values	Conclusion
Application rate 25 kg/ha – single application					
Orchard BBCH 10-19[1]	**Small granivorous bird "finch" Small seeds 100% seeds**	>435	Not calculated no exposure		Risk below the level of concern for non-threatened and threatened species.
	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates[3]		>2.9[3]	<0.3[3]	**Potentially above LOC for non-threatened and threatened species[3]** **3.4x above LOC for non-threatened species** **6.9x above LOC for threatened species**
Bare soil BBCH <10[2]	**Small granivorous bird "finch" Small seeds 100% weed seeds**		Not calculated no exposure		Risk below the level of concern for non-threatened and threatened species.
	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates[3]		>1.6[3]	<0.6[3]	**Potentially above LOC for non-threatened and threatened species[3]** **6.3x above LOC for non-threatened species** **12.5x above LOC for threatened species**
	Small omnivorous bird "lark" Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods		>7.3	<0.13	Below LOC for non-threatened species **Potentially above LOC for threatened species** **0.9x below LOC for non-threatened species** **1.9x above LOC for threatened species**

[1] Orchard scenario (BBCH 10-19) used as surrogate for kiwifruit and apples since hydrogen cyanamide is applied prior to bud break (ie up to BBCH 09), however no specific scenario is available

[2] Bare soil scenario used as surrogate for applications to kiwifruit and apples.

[3] Values in grey are included but no residue data was updated (since seeds are not included in these scenarios) and risks are the same as in the previous table.

Table 76: TER values for acute dietary risk assessment range using a refined endpoint and seed contamination levels 25 kg ai/ha

Crops & BBCH class	Generic focal species[1]	Worst-case/ best-case	TER ratio	RQ values	Risk Range
Application rate 25 kg/ha – single application					
Orchard BBCH 10-19[1]	Small granivorous bird "finch" Small seeds 100% seeds	Worst-case TER, default RUD	>0.8	<1.3	**Potentially above LOC for non-threatened and threatened species** **12.5x above LOC for non-threatened species** **25x above LOC for threatened species**
		Best-case TER, no seed residues	Not calculated no exposure		Below LOC for non-threatened and threatened species
	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates	NA	>2.9	<0.3	**Potentially above LOC for non-threatened and threatened species** **3.4x above LOC for non-threatened species** **6.9x above LOC for threatened species**
Bare soil BBCH <10[2]	Small granivorous bird "finch" Small seeds 100% weed seeds	Worst-case TER, default RUD	>0.7	<1.4	**Potentially above LOC for non-threatened and threatened species** **14.3x above LOC for non-threatened species** **28.6x above LOC for threatened species**
		Best-case TER, no seed residues	Not calculated no exposure		Below LOC for non-threatened and threatened species

Crops & BBCH class	Generic focal species[1]	Worst-case/ best-case	TER ratio	RQ values	Risk Range
	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	NA	>1.6	<0.6	**Potentially above LOC for non-threatened and threatened species** **6.3x above LOC for non-threatened species** **12.5x above LOC for threatened species**
	Small omnivorous bird "lark" Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods	Worst-case TER, default RUD	>1.0	<1.0	**Potentially above LOC for non-threatened and threatened species** **1.4 – 10x above LOC for non-threatened species** **2.7 – 20x above LOC for threatened species**
		Best-case TER, no seed residues	>7.3	<0.13	

[1] Orchard scenario (BBCH 10-19) used as surrogate for kiwifruit and apples since hydrogen cyanamide is applied prior to bud break (ie up to BBCH 09), however no specific scenario is available.

[2] Bare soil scenario used as surrogate for applications to kiwifruit and apples.

[3] Values in grey are included but no residue data was updated (since seeds are not included in these scenarios) and risks are the same as in the previous table.

Table 68: TER values for reproductive risk assessment (TWA = 0.53; MAF = 1) kiwifruit (high rate)

Crops & BBCH class	Generic focal species[1]	Toxicity endpoint value (mg/kg bw/d)*	TER ratio	RQ values	Conclusion
Application rate 25 kg/ha – single application					
Orchard BBCH 10-19[1]	Small granivorous bird "finch" Small seeds 100% seeds	13.3	0.1	19.0	**Above LOC for non-threatened and threatened species** **10 – 50x above LOC for non-threatened species** **20-100x above LOC for threatened species**
	Small insectivorous/worm feeding species "thrush" ground invertebrates with interception 100% soil dwelling invertebrates		0.5	3.9	
Bare soil BBCH <10[2]	Small granivorous bird "finch" Small seeds 100% weed seeds		0.1	21.4	
	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates		0.2	11.1	
	Small omnivorous bird "lark" Combination (ground invertebrates without interception) 50% seeds, 50% ground arthropods		0.1	15.4	

* Normally the NOAEL has to be converted from units of ppm (mg/kg diet) to mg/kg bw/d. In the first instance a factor of 0.1 is used for such conversion. If specific information is available from the test reports, this is preferable. When reported as ppm in the studies, daily dose (mg/kg/d) = [Concentration in food (mg/kg) * Daily food consumption (g/bird/d)] / body weight (g) (over the entire exposure period).

[1] Orchard scenario (BBCH 10-19) is the representative scenario for kiwifruit and apples. Hydrogen cyanamide is applied prior to bud break (ie. up to BBCH 09), however no specific scenario is available for the early BBCH stages for kiwifruit and apples.

[2] Bare soil scenario used as scenario for applications the early stage of kiwifruit and apples. It is unlikely there will be no crop interception by the kiwifruit vines and fruit trees, while this scenario does not include crop interception.