Application for the Reassessment of a Hazardous Substance under Section 63 of the Hazardous Substances and New Organisms Act 1996

Name of Substance(s):

Water dispersible granule or wettable powder containing 750 g/kg quintozene

Application Number:

ERMA200692

Applicant:
Chief Executive ERMA New Zealand

January 2011

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EXECUTIVE SUMMARY

Key Issues

The application

This application is made by the Chief Executive of ERMA New Zealand under the Hazardous Substances and New Organisms Act 1996 for the reassessment of 'water dispersible granule or wettable powder containing 750 g/kg quintozene'.

The reason for this reassessment is that the AMVAC (the US manufacturer) has confirmed that quintozene and the only product currently registered which matches that above substance approval, Terraclor 75WP, is contaminated with "dioxin" (toxicologically significant polychlorinated dibenzo para dioxins and polychlorinated dibenzofurans).

The reassessment process

The Authority approved an application for grounds to reassess the approval for the substance containing quintozene on the basis of its dioxin contamination. ERMA New Zealand has prepared this application for the reassessment quintozene and it dioxin contaminant. Following a submission and hearing process (if requested), the Authority will make a decision on the future use of the approved substance containing quintozene in New Zealand. The Authority's decision will be based on whether or not the positive effects (benefits) of having quintozene available outweigh the adverse effects (risks and costs, including those from its dioxin contaminant) – after taking account of all controls that might be imposed and the likely effects of the substance being unavailable.

Use

Terraclor 75WP is used in New Zealand as a fungicide to treat:

- non grazed turf (recreational turf, specifically golf and bowling greens); and,
- ornamental and vegetable seedlings (or soil) and flower bulbs, prior to or shortly after planting.

Classification

The substance 'water dispersible granule or wettable powder containing 750 g/kg quintozene' is classified as in Table ES1 (see Section 3.5 for details). Since the main reason for the reassessment is the availability of new information relating to the dioxin contamination of the product, ERMA New Zealand did not thoroughly review the classification of quintozene.

No changes are proposed to the current classifications of 'water dispersible granule or wettable powder containing 750 g/kg quintozene' as a result of this reassessment.

Table ES1: Summary of the classifications of quintozene 'water dispersible granule or wettable powder containing 750 g/kg quintozene'

Hazard Class	Quintozene (Approval # HSR000742)
Eye irritancy	6.4A
Contact sensitisation	6.5B
Target organ systemic toxicity	6.9B
Aquatic ecotoxicity	9.1A*
Terrestrial invertebrate ecotoxicity	9.4A*

* These classifications were not reviewed

Overseas regulatory status

Country	Review Outcome
Australia	In April 2010, the Australian Pesticides and Veterinary Medicines Authority (APVMA) suspended the approvals of quintozene and subsequently all products containing quintozene for one year, due to concern about dioxin contamination. A review is currently being undertaken to determine the longer term regulatory status of quintozene and substances containing it in Australia. This review is expected to be completed by in April 2011.
United States	The United States Environmental Protection Agency (US EPA) carried out a review of quintozene in 2006. The US EPA expressed concern about the persistence and bioaccumulative properties of quintozene. The uses of quintozene that were retained following from the review are: • the use on flower bulbs; • the use on cole crops to control clubroot; • the use as a seed treatment.
Canada	The Pest Management Regulatory Agency (PMRA) completed a review of quintozene in 2010. Quintozene use on recreational turf was to be prohibited from 31 December 2010, but limited use of quintozene on cole crops and for ornamental bulb dipping will remain permitted uses.
European Union (EU)	Quintozene cannot be used as a pesticide in the EU. Concerns were raised around the risk to non-target organisms, operators and consumers and regarding the persistence of quintozene.

The concerns addressed in the European and North American reviews largely related to the risk relating to the quintozene active ingredient rather than its dioxin contaminant. The Australian review is focusing on the dioxin contamination.

Non-negligible adverse and positive effects

Adverse and positive effects were assessed in relation to the continued use of quintozene and its dioxin contaminant with existing controls in place.

Non-negligible adverse effects were identified for human health both from quintozene and its dioxin contaminant.

Non-negligible adverse effects were on the environment for the aquatic ecosystem, terrestrial vertebrates and invertebrates were identified. A qualitative assessment identified that the risk from the dioxin contaminant could not be assessed, but is considered to be potentially non-negligible due to the persisten and bioaccumulative properties of the dioxin contaminant.

Area of non-negligible risk	Uses (refer to section)	Details of non-negligible risks
Ecotoxicity risks[1]		
Aquatic environment	Turf	Acute and chronic risks to fish in the freshwater environment from a single application are high. Acute risks to invertebrates from a single application are medium; however a high acute risk is seen from multiple applications. The chronic risks to invertebrates are high.
	Seedlings	Acute risks to fish are medium. Acute risk to invertebrates is low. Chronic risks to fish and invertebrates are high.
	Soil	Acute and chronic risks to fish in freshwater environment from a single application are high. Acute risks to invertebrates are medium. Chronic risks to invertebrates are high.
Ground water	Turf, Seedlings, Soil	A risk of contamination of groundwater from the use of quintozene has been identified especially on soils with low organic matter (e.g. sandy soils).
Birds	Turf, Seedlings, Soil	Chronic risks to birds were not able to be fully evaluated due to a lack of data.
Terrestrials invertebrates (bees)	Turf, Seedlings, Soil	Risk to bees from single application on turf, seedlings and bulbs were not able to be fully evaluated due to a lack of data.
Human health		
Operators	Turf, Seedlings, Soil, Seed boxes	Risks to health of operator during mixing, loading, application even when full PPE is used both from quintozene and from the dioxin contaminant. While risks are lower for low use rate and frequencies (turf/tomatoes), the dioxin risks are not considered non negligible because of its persistence in the body.
	Bulbs	Risks to health of operator during bulb dipping (and non dispersive seed treatments), and potential subsequent health risks due to contamination of equipment both from quintozene and from the dioxin contaminant. There is the potential for contamination which may result in exposure risks

[1] Note that there is no reference to use for seed boxes or bulb dipping in the ecotoxicity risk section, because provided the user undertakes responsible handling and disposal, ecotoxicity risks from these non dispersive uses are low, and no controls to address ecotoxicity risks are needed.

Area of non-negligible risk	Uses (refer to section)	Details of non-negligible risks
		from dioxin long after application.
Re-entry workers	Turf, Seedlings, Soil	Risks to health of re-entry workers from use of quintozene on turf and seed beds in the field, both from quintozene and its dioxin contaminant.
Bystanders	Turf, Seedlings, Soil	Risks to health of bystanders are high for use of quintozene on turf and seed beds in the field due to quintozene and dioxin exposures. While risks are lower for low use rate and frequencies (turf/tomatoes), the dioxin risks are not considered negligible due because of its persistence in the body.

No potentially significant adverse or positive effects on society, community, or on the market economy were identified.

In terms of Māori interests, ERMA New Zealand considers that retaining the current approvals for the substance containing quintozene with its dioxin contaminant would be inconsistent with the principle of active protection.

No potentially significant positive effects from the use of quintozene (with its dioxin contaminant) were identified in respect to human health or the environment.

Alternative fungicides were identified by ERMA New Zealand and by industry representatives, although they were reported to be less effective than quintozene. The alternatives are often of high acute toxicity, but they are not contaminated with dioxin which is considered to be of greater concern than these alternatives.

Revised controls

ERMA New Zealand considered the effect on the non-negligible risks of application of revised controls (Section 6), and in which quintozene would be used only in a non-dispersive manner for seedling and bulb treatment.

ERMA New Zealand took into account the persistent and bioaccumulative properties of quintozene and its dioxin contaminant and concluded that the adverse effects could not be adequately managed with the revised controls in place.

The recommendations set out below are preliminary. An important part of the reassessment process is consideration of public submissions on the application, which may provide information that is not currently available to ERMA New Zealand. The impact of any public submissions on these recommendations will be assessed and considered alongside the application.

Preliminary recommendation

ERMA New Zealand proposes the following preliminary recommendation to ensure that the risk for people and the environment is minimised:

- All quintozene uses shall be revoked, on the basis that:
  - there are risks to the environment that cannot be managed in any other way;
  - numerous alternative products are available for all of the plant protection label uses;
  - there is significant risk to operators posed during application and re-entry into treated crops and turf, and for bystanders from dispersive uses, generally these risk arise both from quintozene and the dioxin contaminant;
  - there is uncertainty regarding the length of time taken for levels of quintozene and its dioxin contaminant to reduce to acceptable levels;
  - the dioxin contaminant, contributes to the risks associated with exposure to the approved substance which are high except for the lowest use rates and frequencies, and ERMA New Zealand does not consider that risk assessment can adequately take into account the long term contamination issues that arise from use of the substance contaminated with dioxin;
  - international considerations support the removal of an avoidable source of persistent organic pollutants (dioxin), which during use will be released to the environment (even from the non dispersive uses);
  - it is consistent with New Zealand's commitments under the Stockholm Convention on Persistent Organic Pollutants;
  - use of quintozene does not provide any significant level of benefit.

Based on this recommendation ERMA New Zealand proposes that:

- **the approval for the quintozene-containing substance (HSR000742) shall be revoked.**

Submissions

Submissions are now invited on the above recommendations. In particular, ERMA New Zealand would like information on the following:

- comment on the accuracy of the uses assessed;
- comment on whether the recommendation is justified, based primarily on concern relating to the dioxin contaminant in quintozene;
- input is sought from Māori to confirm ERMA New Zealand's understanding of their concerns;
- information on use patterns which may enable refinement of the human health risk assessment;
- data to allow refined, higher tier environmental assessments to be undertaken for the risks posed to birds and bees;
- data to allow risk assessment on aquatic and terrestrial plants, soil dwelling organisms and terrestrial invertebrates (other than bees);
- response on whether there should be a phase out period for use of quintozene if the approval is revoked.

Submissions on this application must be made within a 30 working day period. Electronic responses using the form on our web site are encouraged. Please return your submission, whether electronic or by post, fax or email to:

ERMA New Zealand
PO Box 131
Wellington
Fax: 04 914 0433
Email: submissions@ermanz.govt.nz
www.ermanz.govt.nz

All submissions must be received by **16 March, 2011.**

Submissions must state the reasons for making the submission and state whether the submitter wishes to be heard at a public hearing. The submission may also state any decision sought.

For more information on the reassessment process see http://www.ermanz.govt.nz

SECTION ONE – THE APPLICATION

1.1 Background to the application

1.1.1 This is an application for the reassessment of the substance 'water dispersible granule or wettable powder containing 750 g/kg quintozene' prepared by ERMA New Zealand under section 63 of the Hazardous Substances and New Organisms Act ('the Act').

1.1.2 On 14th October 2010, the Environmental Risk Management Authority ('the Authority') decided that grounds exist for the reassessment of the substance containing quintozene. In reaching its decision the Authority noted the following:

- Formulations containing quintozene have been registered for use in New Zealand since 1987. Currently, one product is registered for horticultural use in New Zealand (Terraclor 75WP);
- AMVAC (the US manufacturer) has confirmed that quintozene and the only product currently registered which matches approval HSR000742, Terraclor 75WP, is contaminated with "dioxin" (toxicologically significant polychlorinated dibenzo para dioxins and polychlorinated dibenzofurans);
- Contamination of the formulation containing quintozene with dioxin was not previously known to ERMA New Zealand and no assessment of the significance of the dioxin contamination levels has previously been undertaken;
- Overseas regulatory action has led to the suspension of products containing quintozene in Australia pending further review of the human health risks presented by its dioxin contaminant. In addition, quintozene has been withdrawn/phased out in Europe and the range of use patterns permitted has been severely restricted in North America; and
- The reassessment of the formulation containing quintozene aligns with the principles of the ERMA New Zealand Risk Reduction strategy.

1.2 Preparation of the application

1.2.1 In preparing this application, ERMA New Zealand sought information from importers and users regarding:

- use patterns including 'off label' uses;
- alternatives;
- benefits from the use of the substance in New Zealand; and
- lifecycle information.

1.2.2 A full list of the parties contacted for this information is set out in Appendix K.

1.2.3 In response to this pre-application consultation, information was received from:

- AMVAC Chemical Corporation;
- Australian Pesticides and Veterinary Medicines Authority (APVMA);
- Bloomz New Zealand Limited;
- Fruit Fed Supplies;
- Hort Fert Plus Limited;
- New Zealand Food Safety Authority (NZFSA)
- New Zealand Sports Turf Institute.
- Nufarm Limited;
- Nursery and Garden Industry Association;
- Van Lier Nurseries Limited;

1.2.4 ERMA New Zealand did not undertake a detailed review of the hazard classifications of quintozene itself, as the main trigger for this reassessment was the levels of dioxin contamination. However, during this assessment ERMA New Zealand did consider publicly available sources of toxicology and ecotoxicology data, including environmental fate data for quintozene in order to check that the ERMA New Zealand classifications for quintozene generally align with internationally available data. In relation to the dioxin impurity, a well established human exposure criterion set by the New Zealand Ministry of Health was used for the quantitative human health risk assessment.

Confidentiality of information

1.2.5 The main reason for this reassessment is that the formulation of quintozene covered by the approved substance is contaminated with dioxin.

1.2.6 Information on the dioxin analysis of the product has been provided in confidence by the US manufacturer, AMVAC, and is summarised in Confidential Appendix M.

1.2.7 The quantitative human health risk assessment for the dioxin contaminant requires the use of information relating to the concentration of the dioxin in the formulation. Therefore the detailed risk assessment results for the dioxin contaminant is in Confidential Appendix N. The conclusions relating to the human risk assessment for the dioxin contaminant are, nevertheless, summarised in this application.

1.3 Notification and consultation

1.3.1 This application has been prepared by ERMA New Zealand and will be publicly notified for submissions for a 30 working day period. The submissions received, together with the application, will be taken into account by the Authority in considering the reassessment. If requested by any submitter, the Authority will hold a public hearing.

1.4 Substance(s) covered by the application

1.4.1 The single approval for a substance containing quintozene under the HSNO Act is shown in Table 1:

Table 1: Quintozene-containing substance covered by this application[1]

Substance description	Approval number	Trade names[2]	ACVM Approval
Water dispersible granule or wettable powder containing 750 g/kg quintozene	HSR000742	Terraclor 75 WP	P002215

[1] The substance description and approval number is that included on the public register required by Section 20 of the Act.

[2] Currently registered under the Agricultural Compounds and Veterinary Medicines Act.

1.4.2 Approval HSR000742 was granted to this substance transferred to the HSNO Act. At that time two trade name products, Terraclor 75WP and Newturf Quintozene DG Fungicide, were covered by the substance approval. Newturf Quintozene DG Fungicide was registered as a trade name product under the Agricultural Compounds and Veterinary Medicines Act at the time of transfer of substances to the HSNO Act (1 July 2004). The registration has subsequently not been renewed.

1.4.3 After the grounds for a reassessment were established on 14 October 2010 the owner of the registration for Terraclor 75WP, Nufarm Limited, informed ERMA New Zealand that they would not import or release onto the New Zealand market any further stocks of the product pending the outcome of the reassessment. ERMA New Zealand appreciates this voluntary action by the sole registrant.

SECTION TWO – THE RISK MANAGEMENT CONTEXT

2.1 Risk management context

2.1.1 The Authority decides whether to approve or decline hazardous substances based on the requirements of the HSNO Act and the Methodology[2]. The purpose of the Act is to "protect the environment and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms". The Act and the Methodology therefore provide the foundation for the risk management context for the evaluation and review of this application which must be undertaken in accordance with the purpose of the Act.

2.1.2 Section 29 of the Act requires the Authority to consider adverse and positive effects of the substance(s) and to make a decision based on whether or not the positive effects of releasing the substance outweigh the adverse effects of the substance. The relevant adverse and positive effects are those that are associated with the substance.

2.1.3 In particular, in accordance with section 6 of the Act, the following matters have been taken into account in assessing the risks, costs and benefits associated with the use of quintozene in New Zealand:

- The sustainability of native and valued introduced flora and fauna.
- The intrinsic value of ecosystems.
- Public health.
- The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga.
- The economic and related benefits to be derived from the use of quintozene.
- New Zealand's international obligations.

2.1.4 ERMA New Zealand notes that comparison of risks and benefits, for example, an environmental or human health risk compared to a societal or economic benefit, requires value judgement. ERMA New Zealand has taken this into account in making recommendations (Section 7) and the Authority will take it into account in reaching its decision.

2.2 Consideration of risk management scenarios

2.2.1 Risk-benefit analysis is used to assess the adverse and positive effects. Risk-benefit analysis is a comparative tool; thus the results of the assessment of

[2] Hazardous Substances and New Organisms (Methodology) Order 1998 (SR 1998/217).

risks and benefits for one scenario need to be compared against one or more alternative options.

2.2.2 In the HSNO context there are two basic options: the baseline scenario linked to the *status quo* and one or more alternative scenarios. In the case of a reassessment application the *status quo* is the presence of the substance and this is the baseline scenario used here.

2.2.3 For each use of the substance containing quintozene, ERMA New Zealand considered the following risk management scenarios:

a. continued use with the current controls (the baseline scenario);

b. continued use with revised controls;

c. revoking the HSNO approval and prohibiting further use, either immediately, or after a phase-out period.

2.2.4 The assessment of effects is based on the difference between risk management scenario (b) and the baseline and risk management scenario (c) and the baseline. The assessment assumes that the current controls will be complied with and the relevant risks are those that remain after the controls are taken into account.

2.3 Identification and assessment process

2.3.1 ERMA New Zealand identifies the risks and benefits associated with the substance, and then undertakes a scoping exercise to determine which of them are potentially significant. Risks and benefits are identified in terms of the scenarios and this requires identifying the sources of effect (for example, the hazards and benefits), the pathways for exposure, the areas of impact, and the likelihood and magnitude of effect.

2.3.2 The first step in the reassessment is to determine whether or not there are any potentially significant adverse effects. If the adverse effects are negligible, then further analysis is not required. However, if there are potentially significant adverse effects then additional controls may be applied to ameliorate those adverse effects (risk management scenario (b)).

2.3.3 The second step is to assess the risks and benefits that have been identified as being potentially significant. Those risks and benefits that are deemed to be not potentially significant are described, but are not assessed in detail. Assessing risks and benefits involves combining the magnitude (size or value) of an effect and the likelihood of it occurring. Where there is uncertainty about the magnitude of the effect a range of magnitudes may be assessed.

2.3.4 The estimation of magnitude and likelihood is conducted on a qualitative basis informed where possible by quantitative estimates and analysis.

2.3.5 The approach adopted in identifying and assessing risks and benefits (adverse and positive effects) is as described in the ERMA New Zealand technical guides:

- Assessment of Effects of Hazardous Substances and New Organisms on Human Health (ERMA New Zealand, 2000);
- Decision Making: A Technical Guide to Identifying, Assessing and Evaluating Risks, Costs and Benefits (ERMA New Zealand, 2009); and
- Assessment of Economic Risks, Costs and Benefits: consideration of impacts on the market economy (ERMA New Zealand, 2005).

2.3.6 Details of ERMA New Zealand's qualitative risk assessment methodology are set out in Appendix H.

2.4 Consideration of uncertainty

2.4.1 Clause 8 of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology") states that the information used by the Authority when considering an application must be relevant and appropriate to the scale and significance of the risks, costs and benefits associated with the substance.

2.4.2 Clause 29 of the Methodology indicates that when the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance, the Authority must determine the materiality and significance to the application of the uncertainty. Where any scientific or technical uncertainty is not resolved, the Authority must take into account the need for caution in managing the adverse effects of the substance (clause 30).

2.4.3 Where the Authority considers that there is uncertainty in relation to costs, benefits, and risks (including, where applicable, the scope for managing those risks), the Authority must attempt to establish the range of uncertainty and must take into account the probability of the costs, benefits and risks being either more or less than the levels presented in evidence (clause 32).

2.5 Ethical considerations

2.5.1 In reviewing the information provided and identifying and assessing the adverse and positive effects of quintozene, ethical matters relevant to the use of quintozene have been taken into account. Guidance is provided by the ERMA New Zealand Ethics Framework Protocol[3]. This framework acknowledges that individuals and communities hold a range of ethical views. It has been developed as a tool to assist all participants in the ERMA New Zealand decision-making process to:

- ask the 'right' questions in order to identify areas where there are ethical matters to be considered; and
- use the answers to these questions to explore whether and how ethical considerations need to be addressed.

[3] December 2005, ER-PR-05-1 12/05.

2.5.2 The foundation of the framework is a set of ethical principles, supported by procedural standards. The two general principles, which are embodied in the HSNO Act and the Methodology, are:

- respect for the environment; and
- respect for people (including past, present and future generations).

2.5.3 Under these general principles is a set of specific principles expressed as concerns. These are concern for animal welfare, autonomy, co-operation, cultural identity/pluralism, human rights, human dignity, justice and equality, sustainability and wellbeing/non-harm.

2.5.4 The primary mechanisms for supporting the principles outlined in the framework and for evaluating whether or not they are upheld are the procedural standards of honesty and integrity, transparency and openness, a sound methodology, community and expert consultation and a fair decision-making process.

2.5.5 In preparing this application ERMA New Zealand has applied the criteria in the procedural standards listed above to its evaluation and review of all the information available to it. ERMA New Zealand has been conscious of the concerns expressed by parties who have supplied information to assist in the preparation of this application, and their beliefs that are the basis for these concerns. When ethical dilemmas arise ERMA New Zealand has described them in terms of the framework.

2.6 Principles of the Treaty of Waitangi (Te Tiriti ō Waitangi)

2.6.1 Section 8 of the Act requires the Authority, when considering applications, to take into account the principles of the Treaty of Waitangi. Of particular relevance to this application is the principle of active protection affirmed in 1987 by the Court of Appeal in the Lands case.

2.6.2 It refers to the Crown's obligation to take positive steps to ensure that Māori interests are protected, and to consider them in line with the interests guaranteed to Māori in Article II of the Treaty. Specifically the Court noted that "… the duty of the Crown is not merely passive but extends to active protection of Māori people in the use of their lands and waters to the fullest extent practicable" (Cooke, 1987).

2.6.3 The principle of active protection requires this application to provide sufficient evidence to show that the use of quintozene poses no risk of adverse effects to native/endemic species and/or other taonga species, ecosystems and traditional Māori values, practices, health and well-being. In considering the level of uncertainty described in relation to the adverse effects associated with current use, ERMA New Zealand considers that the current uses of quintozene may be viewed as being inconsistent with the principle of active protection.

SECTION THREE – THE SUBSTANCE AND ITS LIFECYCLE

3.1 Quintozene technical grade active ingredient

3.1.1 The chemical identifiers for quintozene technical grade active ingredient are detailed in Table 2.

Table 2: Identity of quintozene technical grade active ingredient

	Summary Information
Active substance (ISO Common Name)	Quintozene
Function	Fungicide
Chemical name (IUPAC)	1,2,3,4,5-pentachloro-6-nitrobenzene
Synonyms	Pentachloronitrobenzene (PCNB)
CIPAC No	78
CAS No	82-68-8
EEC No (EINECS or ELINCS)	201-453-0
APVMA Specification (including year of publication)	Version 1 August 2004[4]

3.1.2 Quintozene (technical active ingredient) has no HSNO approval for use as a chemical in New Zealand and consequently can only be used as a component of the single approved substance. Quintozene technical grade active ingredient cannot be imported.

3.1.3 Only one quintozene-containing product is currently available in New Zealand (see Table 1). This is the substance that is being reassessed in this application.

- Terraclor 75WP is a wettable powder containing 750 g/kg quintozene, marketed for the control of *Rhizoctonia* and *Fusarium* soil fungi in vegetable and ornamental seedlings and non-grazed turf[5].

3.2 Regulatory History in New Zealand

3.2.1 The substance described as 'Water dispersible granule or wettable powder containing 750 g/kg quintozene' was transferred to the HSNO Act in the Pesticides Transfer Notice (1 July 2004).

3.2.2 Two products containing quintozene were transferred to the HSNO Act in July 2004. The trade name products transferred were Newturf Quintozene DG Fungicide and Terraclor 75WP. Both these products were transferred under the

[4] The specification set a maximum content of hexachlorobenzene of 100 mg/kg in quintozene.

[5] ERMA New Zealand accepted bulb treatments are covered by "ornamental seed uses" rather than describing these as an "off label" use.

same substance approval 'Water dispersible granule or wettable powder containing 750 g/kg quintozene', HSNO Approval HSR000742.

3.2.3 No products containing quintozene have been approved under the HSNO Act since transfer.

3.2.4 At the time of transfer information was not available to ERMA New Zealand that either of the transferred quintozene formulations contained dioxin as a contaminant.

3.2.5 Following the regulatory action by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in suspending use of quintozene in Australia due to the present of dioxin as a contaminant, ERMA New Zealand obtained from AMVAC, the manufacturer of Terraclor 75WP, analytical information which indicated that Terraclor 75WP is contaminated with a detectable concentration of dioxin. This risk assessment has considered the health and environmental risk from both quintozene itself and its dioxin contaminant. ERMA New Zealand does not know whether it is possible to manufacture quintozene which does not contain a detectable dioxin concentration.

3.3 Overseas Usage and Regulatory History

3.3.1 *Australia:*
Quintozene is a fungicide registered for use in Australia as a seed dressing, seedling drench, a pre-plant soil-applied fungicide for vegetables, cotton and ornamentals, and as a pre-emergence fungicide for cotton. It is also used to control fungal diseases on bowling greens, golf greens and for a small number of post-emergence uses on lettuce, peanuts, apples and ornamentals.

3.3.2 On 9 April 2010, the Australian Pesticides and Veterinary Medicines Authority (APVMA) suspended the approvals of quintozene due to the presence of an undeclared contamination of the product with dioxin, and subsequently, on 12 April 2010, suspended all products containing quintozene for the same reason. The suspension remains in effect until 12 April 2011. During the period of the suspension a review is being undertaken by the APVMA to determine the health risk posed by the dioxin contaminant and the appropriate regulatory response. The outcome is expected on 11 April 2011.

3.3.3 *USA:*
United States Environmental Protection Agency (US EPA) carried out a review of quintozene in a Reregistration Eligibility Decision (RED) in 2006 (for pentachloronitrobenzene, PCNB[6]). Essentially the outcome was retention of the use on: flower bulbs; cole crops to control clubroot; use as seed treatment; and the revocation of the other applications. The US EPA expressed concern about the persistence and bioaccumulative properties of quintozene itself including in relation to long range transport.

[6] PCNB is an abbreviation for pentachloronitrobenzene, a synonym for quintozene.

3.3.4 Quintozene was originally registered in the United States in 1964. Quintozene was registered for use as a fungicide on a variety of vegetable, and field crops as well as on turf and ornamentals. It was also used as a seed treatment on several field crops including cereals, rice, vegetable crops and cotton.

3.3.5 *Canada:*
The Pest Management Regulatory Agency (PMRA) in Canada completed a review of quintozene with the decision document dated 24 June 2010 (PMRA, 2010). Quintozene was registered in Canada for control of fungal diseases on cole crops, ornamentals and turf. The US EPA RED was cited in support of the PMRA review.

3.3.6 Quintozene use on recreational turf was to be prohibited from 31 December 2010. Very limited continued use of quintozene on cole crops and for ornamental bulb dipping will remain permitted uses in Canada.

3.3.7 *European Union (EU)*
The EU decided not to include quintozene in Annex I[7] to Directive 91/414/EEC in 2000.

3.3.8 Based on the information available to the EU it was concluded that a risk of non-target organisms exposed to quintozene cannot be excluded. There was also concern about the persistence of the quintozene itself and about the safety of operators and consumers applying quintozene.

3.3.9 The main notifier advised that it no longer wished to support the use of quintozene as an active ingredient in the EU. Consequently quintozene is not included in EU Annex I.

3.3.10 The concerns addressed in the European and North American reviews largely related to the risk relating to the quintozene active ingredient rather than its dioxin contaminant. The Australian review is focusing on the dioxin contamination.

3.4 Mode of action

3.4.1 Quintozene is an organochlorine fungicide. As a fungicide quintozene interferes with mitotic division and suppresses the sporulation.

3.5 Review of hazardous properties

3.5.1 The physico-chemical properties of quintozene and its formulations are described in Appendix A**.**

3.5.2 The environmental fate of quintozene is summarised in Appendix B.

[7] Any pesticide active ingredients approved for use in member EU jurisdictions must be listed on this Annex I. A decision to remove an active ingredient is not an irreversible decision, but agreement to reinstate it would need to be gained before a product containing it could be used in the EU.

3.5.3 Quintozene and its impurities and degradation products are found to be very persistent in the environment and display a high potential to accumulate in fatty tissue. The half-life of quintozene in soil is 1052 days for total residues. The bioconcentration factor (whole fish) is 1100, which means there is a high potential for quintozene to bioaccumulate.

3.5.4 In water photodegradation is expected to be a significant route of dissipation of quintozene in the environment. When the substance is present in clear, shallow, surface water in a non-adsorbed state the half-life is equal to or less than 2.5 days. Hydrolysis is not important as a means of degradation (quintozene is chemically stable).

3.5.5 Quintozene was found to be highly volatile and it was determined that a significant amount of quintozene could volatilise from soil and undergo long-range transport. Residues of quintozene have been detected in locations in the USA where it is not used. Based on its vapour pressure, quintozene will exist almost exclusively in the vapour phase in the atmosphere. A photodegradation DT_{50} of 2200 days for quintozene in the atmosphere was estimated.

3.5.6 The environmental effects of quintozene are summarised in Appendix E. Quintozene is very ecotoxic to aquatic life and to bees according to some data.

3.5.7 The toxicology of quintozene is summarised in Appendix F.

3.5.8 Quintozene is an eye irritant, a contact sensitiser and a target organ systemic toxicant from repeated oral exposure.

3.5.9 Quintozene active ingredient and the product matching the approved substance containing quintozene contains dioxin as a contaminant, so the hazardous properties of the dioxin contaminant also need to be taken into account. The hazardous properties of dioxin are discussed in Appendix F. The dioxin contaminant is a proven human carcinogen, a human reproductive and developmental toxicant and a systemic target organ toxicant. Furthermore dioxin has a long half life in the human body, of approximately 7 years. This means that it is estimated to take 7 years for half of an absorbed dose of dioxin to be excreted.

3.6 Classification

3.6.1 The HSNO classifications (ERMA, 2008a) for the quintozene containing formulation are shown in Table 3. The data on which these classifications are based are shown in Appendix D (ecotoxicity) and Appendix F (human health). The data in these appendices relate to the classification of the quintozene technical grade active ingredient. Although quintozene itself does not have a HSNO approval, it has been classified in ERMA New Zealand's internal database in order to classify the approved substance. The classification of quintozene is the same as that of the mixture in Table 3, because the quintozene component drives all the classifications.

3.6.2 As indicated in the grounds for reassessment document the fundamental reason for the reassessment is the availability of new information relating to the dioxin

contamination of the product. Consequently the ERMA New Zealand did not embark on a detailed review of the classification of quintozene itself, but did review the readily available international reviews. The reviews did not indicate that the current classifications are out of line with other regulators with the possible exception of that for terrestrial invertebrates (9.4A). ERMA New Zealand has not reviewed the class 1, 2, 3, 4, 5 and 8.1 classifications, but is not aware of any information to suggest any change is required.

3.6.3 No changes are proposed to the current classifications of 'water dispersible granule or wettable powder containing 750 g/kg quintozene' as a result of this reassessment.

Table 3: Hazard classification of 'water dispersible granule or wettable powder containing 750 g/kg quintozene'

Hazard Class/Subclass		**Water dispersible granule or wettable powder containing 750 g/kg quintozene**
Class 1	Explosiveness	No
Class 2, 3 & 4	Flammability	No
Class 5	Oxidisers/Organic Peroxides	No
Subclass 8.1	Metallic corrosiveness	No
Subclass 6.1	Acute toxicity (oral)	No
Subclass 6.1	Acute toxicity (dermal)	No
Subclass 6.1	Acute toxicity (inhalation)	No
Subclass 6.3/8.2	Skin irritancy/corrosion	No
Subclass 6.4/8.3	Eye irritancy/corrosion	6.4A
Subclass 6.5A	Respiratory sensitisation	ND[*]
Subclass 6.5B	Contact sensitisation	6.5B
Subclass 6.6	Mutagenicity	ND
Subclass 6.7	Carcinogenicity	ND
Subclass 6.8	Reproductive/ developmental toxicity	ND
Subclass 6.9	Target organ systemic toxicity	6.9B
Subclass 9.1	Aquatic ecotoxicity	9.1A[#]
Subclass 9.2	Soil ecotoxicity	ND
Subclass 9.3	Terrestrial vertebrate ecotoxicity	No
Subclass 9.4	Terrestrial invertebrate ecotoxicity	9.4A[#]

[*] ND = No data

[#] These classifications were not reviewed.

3.7 Lifecycle

Manufacture, importation, transport and storage

3.7.1 Quintozene is currently imported into New Zealand as a component in the formulated substance Terraclor 75WP. The existing approval for the substance containing quintozene covers import or manufacture, which would include repackaging and relabeling.

3.7.2 If manufacture of formulations containing quintozene were to occur in New Zealand, a separate approval for quintozene (active ingredient) would be required to allow the import of the active ingredient into New Zealand.

3.7.3 The registrant has provided the following information (Table 5) regarding the current lifecycle of Terraclor 75WP in New Zealand:

- Terraclor 75WP is imported into New Zealand in 25kg packages;
- The substance is distributed around New Zealand primarily by road transport;
- No repackaging currently occurs in New Zealand.

Table 4: Transport labelling requirements for Terraclor 75WP*

	Labelling requirement
UN Number	UN3077[8] (quintozene)
UN Transport Hazard Class	9
UN Packing Group Number	III

* In accordance with UN Model Regulations annexed to the 16th revised edition (2009) of the Recommendations on the Transport of Dangerous Goods

New Zealand Usage of quintozene

3.7.4 The formulation containing quintozene is currently labelled for use as a plant protection product for the control of soil fungi in vegetable and ornamental seedlings, and non-grazed turf (Table 5). ERMA New Zealand accepted bulb treatments are covered by "ornamental seed uses" rather than describing these as an "off label" use.

3.7.5 A review of current use suggests that although quintozene is used reasonably consistently throughout the year, large quantities of quintozene are not used. The manufacturer has indicated that the product is mostly used in April and May.

3.7.6 Information from parties contacted during the preparation of this application (Appendix K) indicates that Terraclor 75WP is used all year round on vegetable and ornamental seedlings, typically the autumn and winter seasons for *Fusarium* control on turf and the use of Terraclor 75WP on bulbs for export is largest around the months of October/November.

[8] UN3077 is for ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. The technical name (quintozene) must be provided on the documentation.

Table 5: Plant protection product application information for Terraclor 75WP

Soil Fungi	Crop	Rate active ingredient / ha.	Frequency/year	Comments
Brown patch and *Fusarium*	Turf (not grazed)	22.5 kg/ha	1 - 4 times (Interval 30 days)	
Rhizoctonia and *Fusarium*	Ornamental/vegetable seedlings, bulbs Pre-sowing/planting	90 kg/ha	1 per crop	maximum of 4 crops /year
Rhizoctonia and *Fusarium*	Ornamental/vegetable seedlings, bulbs Post planting	1.275 kg/ha	1 per crop	maximum of 4 crops /year

3.7.7 Use information was requested from industry bodies during the preparation of this application. Responses from New Zealand industry bodies have provided the following information:

- Terraclor 75WP is available in 25 kg pack sizes[9].
- Terraclor 75WP is used throughout New Zealand.
- Use by the public is unlikely due to the pack size and the use is further restricted by the approved handler requirements[10].
- The registrant notes the substance is likely to be mostly used on turf throughout the year.
- Terraclor 75WP is considered to be a key product for the export of lily bulbs. The registrant considers this substance to be the only registered product available in New Zealand for the control of diseases on lily bulbs.
- Terraclor 75WP is primarily used on bowling greens and golf courses. It is, however, normally not used on sports turf (playing fields).
- There is no specific recommendation for the use of respiratory protective equipment on the label however one company indicated that a breathing apparatus is used during spraying.
- Terraclor 75WP can be alternated with other fungicides such as chlorothalonil, iprodione, mancozeb, propiconazole, carbendazim, thiophanate methyl, fludioxonil on turf; however, the New Zealand Sports Turf Institute indicates that Terraclor 75WP is the most effective product to control *Fusarium*.
- One user also indicated that depending on the prevalence of *Rhizoctonia*, Terraclor 75WP can be alternated with Kocide 2000LF, Colliss and Taratek 5F.

[9] According to some users the product is available in 2 kg packages, but this information is out of date. Terraclor 75WP was previously available in 2 kg pack sizes, however the registrant indicated only 25 kg pack sizes were available when they voluntarily stopped release onto the market.

[10] ERMA New Zealand notes that the approved handler requirement does not prevent domestic.

- No response was received from PGG Wrightson Turf, Horticulture New Zealand and Royal Van Zanten Flower Bulbs. ERMA New Zealand recognises that a tight timeframe for response during the pre-application period was imposed.

3.7.8 ERMA New Zealand looks forward to further input from all interested parties during the submission period.

3.8 Incidents

New Zealand Incidents

3.8.1 No incidents involving quintozene are recorded on ERMA New Zealand's incident database.

3.8.2 The National Poison Centre has advised ERMA New Zealand that since 2002 the centre has not received any calls relating to quintozene or Terraclor 75WP.

3.8.3 ERMA New Zealand considers that only a small number of recorded incidents involving quintozene may be expected due to its low acute toxicity and the small quantity used.

Overseas Reports

3.8.4 Several overseas incidents have been reported in US EPA RED (US EPA 2006). Between 1993 and 1998 41 cases of quintozene exposure were reported to the American Association of Poison Control Centers. Fifteen of the individuals were seen in a health care facility and one was hospitalised. The California Pesticide Illness Surveillance Program reported 30 incidents between 1982 and 1997. Most incidents involving quintozene were issues with mixture with other pesticides. Between 1984 and 1991 the National Pesticides telecommunications Network reported 16 human and 5 animal incidents associated with quintozene.

3.8.5 In the US EPA RED it was stated that these numbers are relatively small compared to other pesticides for which incidents have been reported.

3.8.6 Interpretation of the significance of these reports needs to take account of the different application methods and controls that may be applied compared to New Zealand. Some of the incidents may have arisen from practices not used in New Zealand. However, in most cases it is impossible to establish such differences from the available reports. ERMA New Zealand therefore concludes that, although incidents have been reported overseas, it is not possible to determine their relevance to New Zealand.

3.9 Uses

3.9.1 To evaluate the risks from use of quintozene as a plant protection product, the uses set out in Table 6 were identified.

Table 6: Uses for quintozene

Use	Method of application	Application rate (product)	Application rate (quintozene)*	Frequency
Turf	Assumed to be low boom	30 g/10 m^2 in 5 litres of water, equivalent to 30kg/ha.	22.5 kg a.i./ha in 5000 litres of water.	Monthly
Seedlings (post-planting)	Back pack, low target	50g in 100 L water, apply 100 - 200ml per plant	Rate /hectare calculated to be 1.275 kg a.i./ha (based on tomato density of 17,000 plants/ha).	Once per crop, 4 crops/year/ site. Assuming use on 1 or 20 days/month
Soil (pre-sowing)	Back pack low target or low boom	1.2 kg/100 m^2, equivalent to 120 kg/ha. Worked into the soil to 15 cm, post application.	90 kg a.i./ha Worked into the soil to 15 cm, post application.	Once per crop, 4 crops/year/ site. Assuming use on 1 or 20 days/month
Empty seed boxes	Back pack, low target	12g in 3L per 1 m^2	90 kg a.i./ha	Assumed as for pre-sowing
Bulbs	Manual dipping	No information provided	Modelling of mixing/loading exposures carried out based on use of upper end of 20 – 40L of mixture containing 1% solution of the product in water.	Assuming use on 1 or 20 days/month

* No application rate is given for the dioxin impurity here as the application rate for dioxin was derived from the quintozene application rate using the concentration of the dioxin contaminant.

3.10 Current Controls

3.10.1 The lifecycle and hazardous properties of the quintozene containing formulation are managed through a variety of controls. These controls are prescribed as part of the approval of these substances under the HSNO Act and the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act), and through requirements under the Resource Management Act 1991. These controls are described in detail in Appendix J.

SECTION FOUR – IDENTIFICATION AND ASSESSMENT OF ADVERSE AND POSITIVE EFFECTS (RISKS, COSTS AND BENEFITS)

4.1 Introduction

4.1.1 The baseline scenario for this reassessment is "continued use with current controls".

4.1.2 "Continued use with revised controls" has also been assessed. In this scenario only use in a non dispersive method for bulbs and seeds would be retained, and in addition to this use restriction control measures are proposed to address risks from quintozene and its dioxin contaminant in the treatment area and in waste streams.

4.1.3 "Revocation of the approval for quintozene", the prohibition of all uses of quintozene, is considered in Section 5.1.

4.1.4 The potential sources of risk to human health and to the environment are tabulated in Table 7.

Table 7: Identification of potential sources of risk

Lifecycle Activity	Potential Source of Risk
Importation, repackaging or labelling	An incident during importation, repackaging or re-labelling, resulting in spillage and subsequent exposure of people and/or the environment.
Local transport	Transport or handling incident during transportation or loading/unloading resulting in spillage and subsequent exposure of people and/or the environment.
Storage	Incident during storage, resulting in spillage and subsequent exposure of people and/or the environment.
Use	Exposure to users, bystanders and/or the environment during dilution, mixing or use, or through exposure to residues on treated bulbs, seedlings or turf and from movement of the substance through the environment.
Disposal	Disposal of the substance or containers, resulting in release of the substance and subsequent exposure of people and/or the environment.

4.2 Environment

Introduction

4.2.1 ERMA New Zealand assessed the effects of quintozene to the environment by quantitative modelling. The effects of dioxins on the environment were assessed in a qualitative manner because the necessary information to do modelling is not available to ERMA New Zealand. Further ERMA New Zealand considers it not likely that the effects of dioxins will trigger extra controls in addition to those already needed for quintozene with respect to ecotoxicity risks.

Identification of adverse effects (risks and costs)

4.2.2 At all steps in the lifecycle (Table 7) there is potential for quintozene and its dioxin contaminant to enter the environment. Quintozene is very toxic to the aquatic environment (9.1A fish and crustacea) and terrestrial invertebrates (9.4A). Therefore it has the potential to cause adverse effects in the environment.

4.2.3 In respect to ecotoxicity, the dioxin contaminant is very persistent and bioaccumulative, particularly in birds and fish (including shell fish).

Assessment of potentially significant adverse effects (risks and costs)

Quintozene

4.2.4 ERMA New Zealand assesses the significance of adverse effects by comparing the environmental exposure to the concentration causing effects. The assessment assumes that currentcontrols are in place and are being complied with.

4.2.5 Given the default controls, ERMA New Zealand considers that the adverse effects from quintozene resulting from any incident or spill during importation, repackaging, local transport, storage or disposal would be localised, but could be of **moderate** magnitude particularly if appreciable quantities (such as a 25 kg package of the Terraclor 75WP) got into a waterway. It is **highly improbable** that this would occur. This combination of likelihood and magnitude indicates a **negligible** risk. Therefore this risk is not assessed further.

4.2.6 ERMA New Zealand modelled likely environmental exposure resulting from three uses of quintozene: turf, seedlings (post-planting) and soil (pre-sowing) see Table 6. ERMA New Zealand did not model environmental exposures resulting from use on seed boxes or bulb dipping, because of the limited environmental exposures from such non-dispersive uses.

4.2.7 Details of the environmental exposure modelling are presented in Appendix C. These estimates of exposure are related to concentrations calculated to cause effects (Appendix D) to derive risk quotients (Appendix E).

4.2.8 This risk assessment showed that thresholds of concern are exceeded for fish, aquatic invertebrates, birds and terrestrial invertebrates in Appendix E. Higher tier modelling could potentially refine these estimated risks, but it is unlikely to reduce the risk quotients by the orders of magnitude required for the risks to become acceptable. Further no data from higher tier studies of some non-target species were available to ERMA New Zealand. The conclusions of the risk assessment are described in the following paragraphs, and are discussed in detail in Appendix E:

4.2.9 Aquatic environment – surface water:

- Fish – freshwater:
  - the acute risk from the use on turf (1 and 4 applications) and soil (pre-sowing) poses a **high** risk;
  - the acute risk from one application on seedlings (post-planting) poses a **medium** risk;
  - the chronic risks to fish for all three uses modelled: turf, seedlings (post-planting) and soil (pre-sowing) are **high.**
- Crustacea – freshwater:
  - the acute risk from one application on turf and soil (pre-sowing) poses a **medium** risk;
  - the acute risk from four applications onto turf is **high**;
  - the acute risk from one application on seedlings (post-planting) is **low**;
  - the chronic risks to crustacea for all 3 uses modelled: turf, seedlings (post-planting) and soil (pre-sowing) are **high.**
- Crustacea – marine water:
  - the acute risk for all uses modelled: turf, seedlings (post-planting) and soil (pre-sowing) is **high**;
  - the chronic risks were not able to be assessed, as ERMA New Zealand did not have access to relevant toxicity data.
- Algae and plants:
  - Due to a lack of data on aquatic plants, no risk assessment for these species could be carried out.

4.2.10 Aquatic environment – groundwater:

- Given the predicted concentrations in groundwater ERMA New Zealand considers there is a risk for contamination of groundwater especially on soils with low organic matter for all dispersive uses.

4.2.11 Terrestrial environment – birds:

- Acute risks: ERMA New Zealand considers the likelihood of acute mortality to birds to be **low** for all 3 uses modelled: turf, seedlings (post-planting) and soil (pre-sowing).
- Chronic risks:The risk assessment shows a need for higher tier assessment of the chronic risks, but the relevant reproductive toxicity data are not available to ERMA New Zealand.

4.2.12 Terrestrial environment – soil-dwelling organisms:

- No toxicity data for acute and chronic exposure to soil-dwelling organisms are available to ERMA New Zealand. Therefore no risk assessment could be carried out.

4.2.13 Terrestrial invertebrates – bees:

- The risks to bees from single applications for all 3 uses modelled: turf, seedlings (post-planting) and soil (pre-sowing) show that higher tier testing is required, but no data are available to ERMA New Zealand to enable the risk assessment to be carried out.

4.2.14 ERMA New Zealand notes that given the environmental fate properties of quintozene long-range transport is possible. Monitoring data from the US show that residues of quintozene have been detected in locations where it is not used. This contributes to environmental risks from quintozene which are not taken into account by calculating risk quotients. Also, some quintozene degradation product are very persistent and bioaccumulative.

Dioxin contaminant

4.2.15 ERMA New Zealand notes that the quintozene is contaminanted with dioxin. The dioxin contaminant is known to be very persistent in the environment and display a high potential to accumulate particularly in birds and fish (including shell fish). Biomagnification is therefore possible. The models used to identify the risks of quintozene do not take bioaccumulation and the adverse effects of the dioxin contaminant into account, therefore the risk quotients understate the ecological risk.

Overall assessment of environmental effects for the risk management scenario a

4.2.16 ERMA New Zealand considers that there are **non-negligible** risks posed to the environment through use of quintozene.

4.2.17 The levels of ecotoxicity risk posed by the use of quintozene are summarised in Table 8.

Table 8: Summary of environmental risk assessment for use of quintozene (with its dioxin contaminant) with current controls

Lifecycle Stage	Potential adverse effect	Magnitude of Adverse Effects	Likelihood of Adverse Effect Occurring	Level of Risk
Import, manufacture, transport, storage or disposal	Adverse acute or chronic environment effects	Moderate	Highly improbable	Negligible
Use – aquatic environment	Adverse acute or chronic environment effects	Quantitative assessment indicates that use of quintozene poses a **high** acute and chronic risk to fish in the aquatic environment. Quantitative assessment indicates the acute and chronic risks to invertebrates in the freshwater environment are **high** when the substance is applied four times. Use poses a risk to ground water. ERMA New Zealand notes quintozene, its dioxin contaminant		Non-negligible

Lifecycle Stage	Potential adverse effect	Magnitude of Adverse Effects	Likelihood of Adverse Effect Occurring	Level of Risk
		and degradation products are very persistent in the environment and have a high potential to bioaccumulate. ERMA New Zealand also notes the potential for long-range transport of quintozene contributes to environmental risk which is not taken into account by modelling risk quotients.		
Use – terrestrial environment (birds)	Adverse acute or chronic environment effects	Quantitative assessment indicates that use of quintozene poses a low likelihood of acute mortality to birds for all use scenarios modelled. Quantitative assessment indicates that quintozene poses a chronic risk to birds after one application that requires refined assessment or management. Quintozene, and its dioxin contaminant and degradation products display a high potential to accumulate particularly in birds and fish (including shell fish).		Non-negligible
Use – terrestrial environment (bees)	Adverse acute or chronic environment effects	Quantitative assessment indicates that the use of quintozene poses an unacceptable risk to bees.		Non-negligible

Identification of positive effects (benefits)

4.2.18 ERMA New Zealand did not identify any positive effects on the environment from the use of quintozene.

Overall evaluation of risks and benefits to the environment

4.2.19 Given the lack of benefits, the risks to the environment through use of quintozene as a plant protection product outweigh the benefits.

4.3 Human health and safety

Identification of adverse effects (risks and costs)

4.3.1 Each of the lifecycle activities listed in Table 7 has the potential to expose people to quintozene and its dioxin contaminant.

Assessment of potentially significant adverse effects (risks and costs)

4.3.2 ERMA New Zealand assessed the adverse effects of quintozene and its dioxin contaminant assuming the current controls are in place and are being complied with.

4.3.3 Given the default controls, any incidents during repackaging, local transport, storage or disposal would be likely to be localised but could be of **minimal** to **major** magnitude. The likelihood of effects resulting from incidents/spills is considered to be **highly improbable**. This combination of likelihood and magnitude indicates a **negligible** to **low** risk.[11]

4.3.4 ERMA New Zealand modelled likely exposure of people during use of Terraclor 75WP with respect to the quintozene active ingredient and the dioxin contaminant present in the product. The modelled uses are based on those in Table 6. Operator exposures were estimated using the UK Chemicals Regulation Directorate (CRD) interpretation of the German BBA operator exposure model. Worker re-entry exposure was calculated based on the approach used by the UK CRD. Bystander exposures were estimated using a combination of CRD approaches for estimating toddler exposures and the US EPA approach which incorporates soil ingestion by the toddler. Estimates of spraydrift were taken from data on the Australian Pesticide and Veterinary Medicines Authority (APVMA) website which are based on the AgDrift model (APVMA, 2010). Details of the human exposure modelling for quintozene are presented in Appendix G. Details of the human exposure modelling for the dioxin contaminant are presented in Confidential Appendix N.

4.3.5 In relation to some uses, bulb dipping and spray application to seed boxes, directly appropriate exposure models are not available, so ERMA New Zealand adapted approaches from other models. In relation to bulb dipping, the exposure estimates were limited to exposures which would result from mixing/loading activities associated with those use patterns. Therefore the estimated exposure estimates are considered to be under estimates and thus do not reflect the total exposure that would result from that use scenario.

Modelling of dioxin exposures

4.3.6 In relation to dioxin exposure estimates, from Confidential Appendix N, the risk quotient derived in comparison with the tolerable monthly intake (TMI) does not fully reflect the health risk, so further discussion of this is provided here. Unlike the situation for a "normal" estimated exposure to a pesticide active ingredient, for which other sources of contamination with the same substance are relatively unlikely, in the case of dioxin any person has some background exposure from food and environmental sources. Therefore an exposure which represents a significant proportion of the TMI is unacceptable. Firstly because the person already has unavoidable exposure to dioxins, and secondly, because the person, whether they be an operator, a re-entry worker or bystander, should not be exposed to an avoidable dioxin exposure. Therefore,

[11] The ERMA New Zealand qualitative risk matrix based on evaluation of likelihood and magnitude of risk is given in Appendix H.

the concept of an "acceptable" dioxin exposure in comparison with the TMI is different from a value that would normally apply to a pesticide. The estimated intakes for dioxin must be well below the TMI for activities which are undertaken on a regular basis.

4.3.7 An additional difficulty with modelling dioxin exposure is how to compare exposures to activities occurring occasionally (once per month) or regularly (20 days per month) with the TMI. ERMA New Zealand has assumed that exposure only occurs 20 days per month as a worst case scenario. However, it could be argued that this is not fully precautionary for a bioaccumulative toxin like dioxin when compared to the approach used for quintozene (or other pesticide active ingredients). The absorbed dose of dioxin an operator, re-entry worker or bystander receives is likely to be present in the body for a substantial period, so that the repeat exposures contribute to their body burden in way which does not occur for most pesticides. The half life of absorbed dioxins in humans has been estimated as approximately 7 years (see Appendix F). ERMA New Zealand points out that the use of 20 days per month exposure in comparison to the TMI in effect reduces the dioxin exposure in comparison to the TMI, compared to that for the quintozene assessment, which compares a single day's exposure with the permitted daily exposure. This has the impact of reducing the dioxin risk by a factor of 20/30. Given the accumulation of dioxin in the exposed person this approach is not fully precautionary, and results in lower estimated risks from dioxin.

4.3.8 For the soil treatment pre-planting post application "working in" may involve exposure to both quintozene and dioxin in addition to the exposure that has been modeled. Use of PPE (gloves and apron) is desirable if handling soil for such activity but ERMA New Zealand is not able to quantitatively assess either the exposure or whether or not such protection is adequate. While the dioxin is likely to bind to soil organic matter relatively strongly so that it may not be bioavailable, it is very persistent in the environment. On-going use of quintozene contaminated with dioxin is likely, over time to result in contamination of the environment, and disposal of surplus bulb treatment solution could potentially result in the making of "new" contaminated sites in New Zealand, which is clearly highly undesirable. Depending on the nature of the land use, it is possible that such contamination could subsequently give risk to contamination entering the human food chain, particularly if presence of the contamination is not known and the property changes ownership.

4.3.9 Dioxin is recognised as persistent and highly bioaccumulative. ERMA New Zealand has not attempted to assess the significance of the dioxin emissions to the general environment from the use of quintozene, but the potential of environmental dioxin levels ultimately increasing dioxin concentrations in the environment and, in particular, in human food sources such as shellfish, fin fish (from runoff) and wild species used for food sources such as ducks, which may feed on areas treated with quintozene with it dioxin contaminant does exist. ERMA New Zealand considers that such considerations support the view that a precautionary approach to on-going use of quintozene should be taken.

4.3.10 Some of the uses of quintozene are treatments of human food crops as either seeds or very small plants, particularly for common vegetables such as

brassicas and lettuce. ERMA New Zealand has not attempted to estimate whether there is any potential for residues of quintozene or the contaminants it contains to be carried into the mature plants at time of harvest and subsequently consumed. This is a matter for the New Zealand Food Safety Authority to consider if on-going use of quintozene for such crops is permitted.

4.3.11 **Operator Exposure:** The conclusions of this risk assessment for operator exposures are:

Quintozene

Use: Turf boom sprayer (low target)

The operator risk from quintozene from application to turf using a boom sprayer or back pack sprayer without protective equipment are high. Full PPE (chemical resistant gloves, coveralls, hood and visor, coveralls, sturdy footwear and a respirator) during mixing/loading and application reduces the exposure risk for the operators, but does not make them negligible. If application of quintozene was only carried out occasionally (once per month), and full PPE was worn the risk is lower, but is still not reduced to negligible.

Use: Application to field tomatoes

The operator risks from quintozene from application to tomatoes are high without protective equipment. Even if full PPE is worn during mixing and application the exposure risk for the operators are high. If application of quintozene was only carried out occasionally (once per month), and full PPE was worn, the risk is lower, but is not reduced to negligible.

Use: Soil (pre-planting) and seed box application using backpack sprayer)

The operator risk from quintozene is very high without protective equipment and remains so even if full PPE is worn. While the model estimates are for a high level target and the use is likely to be for a low level target ERMA New Zealand does not consider the exposure estimates would be reduced to negligible with a low level target. Due to the high application rates for these scenarios ERMA New Zealand does not consider any controls are available which could reduce the risks to the degree necessary.

Use: Bulb dipping

ERMA New Zealand has no models available for estimating exposures from bulb dipping, so ERMA New Zealand estimated exposures during mixing and loading as a surrogate which will at least estimate part of the associated risk. For the mixing/loading part of the operation, the operator risks from quintozene were assessed as negligible whether PPE was worn or not. However since the mixing/loading estimate is likely to underestimate the true exposure, ERMA New Zealand concludes that the use of PPE to protect the operator should be required. In North America where bulb treatment uses of quintozene are permitted, extensive use of PPE has been required (EPA, PMRA), as discussed in section 5.

Dioxin

Use: Turf boom sprayer (low target)

The operator risk from dioxin if application using either boom sprayer or back pack sprayer occurs on 20 days per month even if full PPE is worn is high. If exposures were to be limited to 1 day per month, and PPE (with or without a respirator) was worn, the dioxin exposure is less than the TMI. As discussed above, however, ERMA New Zealand considers a single application per month even with PPE still represents a non negligible risk due to the persistence of dioxin in the body.

Use: Application to field tomatoes

The operator risks from dioxin from application using a back pack sprayer for tomatoes on 20 days per month are high unless PPE is worn. If application were to be limited to 1 day per month the modelling suggests that even with PPE, dioxin exposure is less than the TMI. Overall ERMA New Zealand considers a single application per month with PPE is be unacceptable due to the particular concerns relating to dioxin persistence discussed above.

Use: Soil (pre-planting) and seed box application (using backpack sprayer)

The operator risks from dioxin treatment of seed beds are high if exposure occurs on 20 days per month even if full PPE (with a respirator) is worn. If exposure was limited to 1 day per month, the dioxin exposure would still be unacceptably high without PPE, but if full PPE (with or without a respirator) is worn the RQ is less than 1 in relation to the TMI for 1 application per month. While with PPE the RQ in relation to the TMI is less than 1 for some uses, ERMA New Zealand does not consider the risk is negligible, due to the particular concerns relating to dioxin persistence discussed above.

Use: Bulb dipping

ERMA New Zealand had no models available for this activity so only estimated the mixing loading exposures, as a surrogate which will at least estimate part of the associated risk. For this part of the operation, the operator risks from dioxin were below the TMI for a worker without PPE carrying out the activity 20 days per month. The mixing loading estimate is likely to substantially underestimate the true operator exposure. ERMA New Zealand does not consider this risk is negligible due to the particular concerns relating to dioxin exposures as discussed above. Furthermore, due to the nature of the dioxin contaminant, particularly its persistence, ERMA New Zealand notes that use of quintozene in a workplace may over time result in an accumulation of residue. While the dioxin exposures estimated here are assumed to apply on the days quintozene is applied, some indirect exposure from residue on seed boxes, in treatment areas (such as wooden benches) and in soil may occur. ERMA New Zealand notes that it is difficult to protect the operator or other staff members from such exposures by use of PPE, since it would be unclear where the residue may be present and for how long.

4.3.12 **Re-entry Exposure:** The conclusions of this risk assessment for re-entry exposures are:

Quintozene

Use: Turf boom sprayer (low target)

The re-entry risks following 2 turf application of quintozene at a 30 day interval even from a low foliar contact activity (mowing and irrigation) were very high without use of PPE, and the magnitude of the risks indicate use of PPE is unlikely to reduce these substantially. The estimate assumed a foliar half life of 35 days (the default value used by the USEPA for quintozene in the absence of data), and any estimated restricted re-entry period would be very long even for this low contact activity.

Use: Application to field tomatoes

A separate re-entry risk calculation was carried out for the post-planting tomato application as the application rate is substantially lower. Nevertheless, even at this lower application rate the re-entry risks were estimated to be unacceptable without PPE and to require a substantial re-entry interval.

Use: Soil (pre-planting) and seed box application using backpack sprayer)

In view of the high re-entry risks from turf and field tomatoes, no model estimates for higher applications rate seed treatment uses were derived, as these will clearly show high re-entry risks.

Use 5: Bulb dipping

Re – entry exposures are not considered relevant to bulb uses.

Dioxin

Use: Turf boom sprayer (low target)

The re-entry risks from dioxin following 2 turf applications of quintozene at a 30 day interval would be high without use of PPE if the worker was exposed during that activity 20 days per month. The magnitude of the risks indicates use of PPE is unlikely to reduce this substantially. ERMA New Zealand notes that due to the persistent nature of the dioxin contaminant, the worker may not need to be exposed to a freshly treated field, but could potentially be exposed repeatedly by re-entering a particular field. The assumption of a foliar half life of 35 days (the default value) may not provide adequate precaution for dioxin contamination, given its persistence in the environment.

Use: Application to field tomatoes

A separate re-entry exposure calculation was carried out for the post-planting tomato application as the application rate is substantially lower. Nevertheless, even at this lower application rate, the exposures for a re-entry worker carrying out activity in a treated crop 20 days per month was estimated to be unacceptable without PPE. As noted previously, this is the case even if the

default foliar half life of 35 days is used which may not include adequate precaution for the dioxin contaminant.

Use: Soil (pre-planting) and seed box application using backpack sprayer)

In view of these high re-entry risks from turf and field tomatoes, no model estimates for the high application rate seed treatment uses were developed, as these will clearly show high re-entry risks.

Use: Bulb dipping

Re – entry exposures are not considered relevant to bulb uses. Nevertheless, ERMA New Zealand notes there may be risks from handling bulbs after treatment, particularly due to the persistent nature of dioxin residues. It may not be common practice to use protective equipment when handling bulbs and this is not currently a HSNO control required under this approval.

4.3.13 **Bystander Exposure:** The conclusions of this risk assessment for bystander exposures are:

Quintozene

Use: Turf boom sprayer (low target)

Bystander risk following turf application of quintozene from two applications at a 30 day interval was non negligible and a buffer zone of 148 m was estimated to be required between the application area and a place where a toddler may be located.

Use: Application to field tomatoes

Bystander risks following application of quintozene to field tomatoes (a single application) were negligible at 8 m, and a buffer zone of 6 m was estimated to be required between the application area and a place where a toddler may be located.

Use: Soil (pre-planting) and seed box application using backpack sprayer)

Bystander risks following soil application of quintozene from a single application were non-negligible and a buffer zone of greater than 300 m was estimated to be required between the application area and a place where a toddler may be located.

Uses: Bulb dipping

Bystander risks are not relevant to bulb uses.

Dioxin

Use: Turf boom sprayer (low target)

Bystander risks from dioxin following turf application of quintozene from two applications at a 30 day interval are considered by ERMA New Zealand to be

non-neglible at a buffer zone 8 m, taking into account the nature of the dioxin contaminant to which the toddler is being exposed.

Use: Application to field tomatoes

Bystander risks from dioxin following application of quintozene to field tomatoes (a single application) were negligible according to the model at 8 m and no buffer zone is needed to a place where a toddler may be located. Nevertheless the comments below about the concerns about persistence of the dioxin contaminant need to be taken into account so ERMA New Zealand considers that toddler risk is non-negligible.

Use: Soil (pre-planting) and seed box application using backpack sprayer)

Bystander risks from dioxin following soil application of quintozene from a single application were non-negligible and a buffer zone of 32 m was estimated to be required between the application area and a place where a toddler may be located.

Use: Bulb dipping

Bystander risks are not relevant to bulb dipping.

Overall assessment of human health effects from risk management scenario (a)

4.3.14 ERMA New Zealand concludes that the human health risks from the quintozene active ingredient from the use of substance containing quintozene are non negligible.

4.3.15 ERMA New Zealand concludes that the human health risks from the dioxin contaminant from the use of substance containing quintozene are non negligible. For all uses ERMA New Zealand concludes the risks are non negligible taking into account the persistence in the human body and the environment of the dioxin contaminant.

Table 9: Summary of human health risk assessment for use of quintozene (with its dioxin contaminant) and with current controls

Lifecycle Stage	Potential adverse effect	Magnitude of Adverse Effects	Likelihood of Adverse Effect Occurring	Level of Risk
Import, transport, storage or disposal	Adverse acute or chronic health effects	Minimal to Major	Highly improbable	Negligible to Low
Use – operator	Adverse acute or chronic health effects	Use of quintozene for turf and seed bed uses pose unacceptably high risks with any of the available levels of PPE, including a respirator, due to risk both from the quintozene and the dioxin contaminant. Use of quintozene for field tomatoes poses a high risk to operators even with full PPE based on the quintozene risks. The dioxin risk are lower based on the modelling, but even for use once per month with PPE, due to the persistence of the dioxin in the body, ERMA New Zealand considers the risk non-negligible. Use of quintozene for bulb dipping based on the exposure estimate for mixing and loading only, was negligible for the quintozene, while the dioxin risk were non- negligible taking into account the persistence of dioxin in the body.		Non-Negligible
Use – re-entry	Adverse acute or chronic health effects	Re-entry into application areas, for turf and field tomatoes, where quintozene has been applied poses a significant risk based on the quinotzene active ingredient and the dioxin contaminant.		Non-negligible
Use – bystander	Adverse acute or chronic health effects	Bystander risks from turf and soil (pre-planting) were high and would require a large buffer zone to protect an exposure toddler both for the quintozene active ingredient and the dioxin contaminant. Bystander risks from use on field tomtatoes were negligible for quintozene and the dioxin based on model estimates, but due to the nature of the dioxin eontaminant ERMA New Zealand considers the risk to be non negligible.		Non-negligible

Identification of positive effects (benefits)

4.3.16 ERMA New Zealand did not identify any positive effects on the human health and safety from the use of quintozene.

Overall evaluation of risks and benefits to human health

4.3.17 The risks to human health from use of quintozene outweigh the benefits.

4.4 Society and communities

4.4.1 It is noted that while in the past Terraclor 75WP was available in 2.5kg packs, the current pack size for this product is 25 kg which essentially means that it is unlikely that it would be used by the general public.

Identification of adverse effects on society and communities

4.4.2 ERMA New Zealand has not been able to find any reports of public concern in New Zealand about the use of quintozene and therefore has not identified any adverse effects on society and communities, other than those associated with health and safety, from the continued use of quintozene and its dioxin contaminants.

4.4.3 In identifying adverse effects on society and communities ERMA New Zealand has focussed on risk management scenario (a), the baseline scenario, and risk management scenario (c), the unavailability of quintozene and its dioxin contaminants. The imposition of additional controls would not be expected to make any significant change to adverse effects on society and community.

4.4.4 However, ERMA New Zealand notes that if the public were aware that the quintozene product contained dioxin as a contaminant then they might have greater concern about the availability of such a product.

4.4.5 Similarly, ERMA New Zealand notes that if quintozene containing dioxin continued to be used in New Zealand there may be social (and economic) effects from the issues around the potential for 'new' contaminated sites discussed in 4.3.8, 6.1.18 and 6.1.19.

Identification of positive effects on society and communities

4.4.6 As noted in Section 3, quintozene is used for the control of soil fungi in vegetable and ornamental seedlings, in flower bulbs and non-grazed turf. Of these, there is amenity value associated with fungi free seedlings and bulbs. However, ERMA New Zealand cannot establish a level of benefit associated with this amenity value.

4.4.7 ERMA New Zealand invites submitters to provide any information they might have on the level of amenity value associated with the continued availability of quintozene.

4.5 The market economy

4.5.1 In preparing this section, ERMA New Zealand consulted with users and Plant & Food Research on the use of quintozene in New Zealand and potential alternatives. One product containing quintozene is currently registered in New Zealand as Terraclor 75WP.

4.5.2 Effects on the market economy are identified and assessed in accordance with the ERMA New Zealand Technical Guide "*Assessment of Economic Risks, Costs and* Benefits*: Consideration of impacts on the market economy*" (ISBN 0-478-21525-8). This guide contains the principles underlying the analysis of effects. And addresses the way in which the application will affect the market economy, as distinct from health, social, ecological and amenity impacts. While it is accepted that there are significant overlaps between these areas, the intent is to provide information to support an understanding of how costs and benefits arise in the traded sector. This will include impacts on the supply of goods through their production, distribution and marketing, and on the domestic and export demand for those goods. In economic analysis terms the paradigm applied is thus one of identifying where there is a sufficient level of benefit to merit approval. This is different to, and in some case more limiting than, the objectives that might normally be associated with economic analysis, such as maximisation of net benefit.

4.5.3 The effects of the substance are considered in terms of the marginal difference between the baseline (risk management scenario (a)) and the non-availability of the substance (risk management scenario (c)). The effects associated with risk management scenario (b) or a set of modified controls would be expected to result in reduced adverse effects and reduced benefits.

4.5.4 This product is not used on pasture, and ERMA New Zealand therefore concludes that there are no potentially significant adverse or positive effects on the market economy from the use of quintozene in the pastoral sector.

Identification of adverse effects on the market economy

4.5.5 ERMA New Zealand did not identify any adverse effects on the market economy from the continued use of quintozene at the present time as long as the relevant MRLs are adhered to. CODEX reports MRLs for quintozene for broccoli, cabbages, sweet peppers, tomatoes, beans, and barley corn and wheat grains. The only crop of relevance to New Zealand at present would appear to be broccoli, and quintozene is only used at early growth stages. However, this does not mean that if quintozene remains available that it could not be used for other crops.

Identification of positive effects (benefits) on the market economy

4.5.6 Terraclor 75WP is registered for use on non-grazed turf. Responses from industry state that it is used on golf greens (but not fairways). There is some contradiction as to whether it is used on bowling greens or not. Responses also indicate that there is a range of alternatives that are either cheaper or of a

similar price. The New Zealand Sports Turf Institute (NZSTI) notes that while Terraclor 75WP is only one of a range of products, some of the other fungicides are not as effective and that this could result in greater loss of golf green turf in some areas with resultant costs of reinstatement. However, the NZSTI also notes that some turf managers successfully use a range of 'cultural practices' in conjunction with alternatives.

4.5.7 Terraclor 75WP is used to control of soil fungi in vegetable and ornamental seedlings, cut flowers and flower bulbs.

4.5.8 Bloomz indicated that they used 10-20kg of Terraclor 75WP on export bulbs, in the form of a drench for bark based media and a pre-plant bulb dip. While other chemicals are available, Terraclor 75WP is considered to be the most effective, and its use is predicated on effectiveness rather than cost. Bloomz indicated that the cost of the crop at risk could be greater than $100,000 per year.

4.5.9 Green Harvest Pacific Ltd has indicated that lily bulb growers do not use Terraclor 75WP, and this is supported by the lack of response from one of the main lily bulb growers. Sandersonia growers and exporters have in the past used Terraclor 75WP, but at least one major grower and exporter has developed alternative mixtures of fungicides and bacteriocides that are proving to be effective (Green Harvest Pacific Ltd). Van Lier Nurseries use Terraclor 75WP for the carnation cut flower crop and considers that if it were not available then the mother plant stock would be at risk as well as the cut flowers. They estimate the potential loss at $30,000 [assumed to be per annum] and five jobs.

4.5.10 HortFert Plus Ltd indicates that they sell about 100kg per year of Terraclor 75WP for use on vegetable and ornamental seedlings. In terms of vegetable plants Terraclor 75WP is used on crops such as brassicas and strawberry plants at young stages. ERMA New Zealand has not received any information about the value of the vegetable crops at risk. Alternatives are available, but are considered to be more expensive and less effective.

4.5.11 In summary, while Terraclor 75WP appears to be a useful product for controlling fungi in a variety of settings, the areas in which it provides the clearest market benefit is in treatment of bulbs. However, while the value of crop at risk is high (estimated at $100,000) ERMA New Zealand does not consider that this represents an accurate marginal value for the positive effect of the availability of Terraclor 75WP and concludes that the positive effect over a number of years is not potentially significant.

4.5.12 ERMA New Zealand notes that there is also value to the cut flower industry but reaches the same conclusion that the positive effect associated with the availability of Terraclor 75WP is not potentially significant on the basis that alternatives are available, even if they might be more expensive and less effective.

Overall evaluation of effects on the market economy

4.5.13 ERMA New Zealand has identified some potential positive effects on the market economy from the continued availability and use of quintozene. These effects relate to businesses involved in commercial bulb growing.

4.5.14 ERMA New Zealand notes that submitters may have additional information about the nature and level of adverse and positive social effects on the market economy from the use of quintozene and invites them to provide any such information they might have.

4.6 Māori interests and concerns

Relationship of Māori to the environment

4.6.1 ERMA New Zealand notes that quintozene triggers a number of hazardous properties giving rise to cultural risk including the deterioration of the mauri of taonga flora and fauna species, the environment and the general health and well-being of individuals and the community.

4.6.2 At recent national hui and wānanga with Māori practitioners of Kaitiakitanga, it is a strong belief by participants that if a substance such as quintozene together with its dioxin contaminant does not have potentially significant or non-negligible benefits to Māori to enhance the mauri of taonga flora and fauna species, whānau[12], hapū[13] and iwi[14] and the overall relationship of Māori to the environment, then in accordance with the principles of Kaitiakitanga, Māori would inclined to decline any such continuation of such a substance and its use in Aotearoa.

Treaty of Waitangi

4.6.3 Section 8 of the Act requires the Authority, when considering applications, to take into account the principles of the Treaty of Waitangi. Of particular relevance to this application is the principle of active protection affirmed by the Court of Appeal in the Lands case (1987).

4.6.4 This principle refers to the Crown's obligation to take positive steps to ensure that Māori interests are protected, and to consider them in line with the interests guaranteed to Māori in Article II of the Treaty. Specifically the Court noted that "… the duty of the Crown is not merely passive but extends to active protection of Maori people in the use of their lands and waters to the fullest extent practicable".

4.6.5 Taking into account the principle of active protection requires this application to provide sufficient evidence to show that the use of quintozene and its

[12] Families

[13] Sub-tribe

[14] Communities

approved formulations pose no risk of adverse effects to native/endemic species and/or other taonga species, ecosystems and traditional Māori values, practices, health and well-being. Having considered the information available in relation to the adverse effects noted above, ERMA New Zealand considers that retaining the current approvals for the substance containing quintozene would be inconsistent with the principle of active protection.

4.7 International obligations

4.7.1 ERMA New Zealand has identified that the Stockholm Convention on Persistent Organic Pollutants, to which New Zealand is a signatory, is relevant to the on-going use of quintozene in New Zealand.

4.7.2 The Stockholm Convention on Persistent Organic Pollutants aims to protect human health and the environment by banning the production and use of some of the most toxic chemicals known to humankind. The Convention became international law in May 2004, was ratified by New Zealand in September 2004, and entered into force for New Zealand on 23 December 2004. Persistent organic pollutants (POPs) are organic compounds that:

- do not break down readily in the environment;
- are capable of long-range transport, bioaccumulate in human and animal tissue (and biomagnify in food chains);
- pose a risk of causing adverse effects to human health and the environment.

4.7.3 The 12 organochlorine (chlorine-containing) chemicals initially listed as POPs under the Convention in 2004 include the following contaminants in quintozene:

- **dioxins and furans** (polychlorinated dibenzo-p-dioxins or PCDDs, and polychlorinated dibenzofurans or PCDFs), and.
- **hexachlorobenzene** as a pesticide and industrial chemical

4.7.4 In 2009, additional compounds added to coverage of the convention included:

- **pentachlorobenzene** (produced unintentionally and used as a chemical intermediate for the production of quintozene, and formerly in dyestuff carriers, as a fungicide and flame retardant, very toxic to aquatic organisms).

4.7.5 In the discussion of this by the UNEP (UNEP, 2008) an alternative manufacturing processes for quintozene was referred to not requiring pentachlorobenzene as a manufacturing intermediate (but using nitrobenzene as a manufacturing intermediate instead).

Dioxins

4.7.6 Dioxins are released to the environment in very small amounts through a number of industrial and domestic activities, particularly the open burning of

wastes. New Zealand is obligated under the convention to take measures to reduce, and where feasible ultimately eliminate, releases of dioxin. Although levels of dioxins in New Zealand foods (including our meats, dairy products and fish) are low and below the World Health Organization guidelines, it is prudent to further minimise our exposure to dioxins where practicable.

4.7.7 As a first measure, the Ministry for the Environment has developed national environmental standards (NES) as regulations under the Resource Management Act 1991. The NES for Certain Air Pollutants, Dioxins and Other Toxics, bans certain activities that produce dioxins and other air toxins. The activities, banned from 8 October 2004, comprise:

- burning insulated copper wire, oil or tyres in the open;
- burning road seal;
- high-temperature incineration of hazardous waste (except for three facilities that have existing resource consents);
- low-temperature waste incineration in schools and hospitals from October 2006 (unless the facility has a resource consent).

4.7.8 In relation to the reassessment of quintozene, the Stockholm Convention is also of relevance due to contamination of the product with hexachlorobenzene and pentachlorobenzene. It is proposed that if ongoing use of quintozene is permitted, restrictions on the concentrations of these contaminants be put in place by means of a quintozene specification.

Conclusion

4.7.9 ERMA New Zealand notes that at the time that this application is being written the Ministry for the Environment is about to publish an update to the national inventory of dioxin emissions. ERMA New Zealand considers that the national commitment to the Stockholm Convention, to reduce dioxin emissions and institute sound management of other POPs, such as HCB and pentachlorobenzene supports the conclusion that use of quintozene should be discontinued.

4.7.10 In relation to the dioxin contamination, many dioxin sources are relatively difficult to restrict due to the emissions being from generalised diffuse combustions sources. Consequently, ERMA New Zealand concludes that it is desirable to discontinue the use of a pesticide contaminated at a significant level with dioxins as such uses contribute to dioxin emissions and are relatively easy to prevent.

4.7.11 A substantial benefit should be associated with the on-going use of quintozene for it to be justified based on the persistence of the dioxin contaminant in particular, but also in relation to the HCB and pentachlorobenzene contaminants.

SECTION FIVE – LIKELY EFFECTS OF QUINTOZENE BEING UNAVAILABLE

5.1 Introduction

5.1.1 ERMA New Zealand considered alternative scenarios that might arise if the use of quintozene was restricted or prevented. In particular, the availability of alternative pesticides was considered. It is noted that the list of alternatives identified may not be a complete representation of all available alternatives, and ERMA New Zealand welcomes any additional information on potential alternative substances.

5.1.2 It is not practical to assess the risk of all alternative products, but a comparison has been made on the basis of hazard profile. Hazard assessment is not an indication of the risk posed by a substance, since exposure is not taken into account, but it can be used as an indicator of the potential to cause effects.

5.1.3 Detailed information on the comparability of the alternative products has not been gathered, in particular:

- relative efficacy;
- the research required to determine if they are indeed suitable alternatives;
- comparability of properties for which quintozene is valued, long lasting good efficacy.

5.1.4 It is noted that restricting the suite of pesticides available may lead to a reduced ability to manage pest resistance.

5.2 Availability of alternative pesticides

5.2.1 Users have identified some alternative products which are listed in Table 10.

Turf

5.2.2 For the use on turf, 12 alternatives of different chemical groups have been identified. However, only six of these substances have a current approval for the use on turf/pasture in New Zealand. According to the ACVM register the substance fenarimol is not registered as pesticide in New Zealand, although it has a HSNO approval.

Ornamental and vegetable seedlings and bulbs

5.2.3 For the use in ornamentals and vegetables ten alternatives from different chemical groups have been identified. Thiram and propiconazole may be alternatives as well. All the substances in Table 10 (seedlings and bulbs) have an approval in New Zealand. The majority have an approval in vegetables and three substances have an approval in ornamentals. A combination product containing etriadiazol and thiophanate-methyl is approved in ornamental plants

to control soil borne diseases like *Rhizoctonia*. Products containing tolclofos-methyl and fludioxonil have an approval to control *Rhizoctonia* in potato.

5.2.4 ERMA New Zealand concludes that there are alternative products for the use on turf. Although users commented that those alternatives may not be as effective in controlling *Fusarium* as quintozene because quintozene provides a longer suppression.

5.2.5 ERMA New Zealand concludes that there are alternative products for the use in ornamentals, vegetables and flower bulbs. However, some additional research may be needed to test crop safety and residues in vegetables because not all alternatives have an approval in vegetables or ornamentals. Users commented that quintozene is the most effective control option.

5.2.6 The alternative active ingredients present a range of hazard profiles, some lower some greater, than quintozene (Table 10). Almost all alternatives are not bioaccumulative. The majority of the alternatives are not rapidly degradable according to the HSNO criteria (a half live in soil of more than 30 days means not rapidly degradable). However, 12 substances have half-lives of less than a year, significantly less than the half-live of quintozene which is almost 3 years.

5.2.7 ERMA New Zealand notes that there are likely to be some risks associated with the use of products that would likely be used as alternatives if the use of quintozene were restricted or prohibited. The majority of the alternative plant protection products have higher toxicity for class 6.1 than the quintozene, but are not contaminated with dioxin which is considered to be of greater concern than these alternative active ingredients.

Table 10: Comparison of alternative plant protection active ingredients

Turf

Active ingredient	Hazard Classification														
	6.1 (O)[2]	6.1 (D)	6.1 (I)	6.4	6.5	6.6	6.7	6.8	6.9	9.1	9.2	9.3	9.4	Bioaccumulative	Rapid biodegradation
quintozene	**No**	**No**	**No**	**6.4A**	**6.5B**	**ND**	**ND**	**ND**	**6.9B**	**9.1A**	**ND**	**No**	**9.4A**	**Yes**	**No**
azoxystrobin	No	ND	C	No	No	No	ND	No	B	A	C	No	No	No	No
carbendazim*	E	ND	No	ND	ND	A	ND	A	B	A	B	No	No	No	No
chlorothalonil*	No	No	B	8.3A	B	No	B	No	A	A	B	B	No	No	No
fenarimol	E	ND	ND	A	No	No	ND	B	B	A	No	No	No	No	No
iprodione	E	ND	No	No	No	No	ND	No	B	A	No	No	No	No	No
mancozeb*	No	No	No	A	B	No	ND	ND	B	A	No	No	No	No	No
prochloraz	D	ND	ND	A	ND	No	ND	No	B	A	No	C	No	No	No
propiconazole[1]	D	ND	ND	A	No	No	No	No	B	A	No	C	No	No	No
tebuconazole	D	No	No	No	No	No	ND	ND	B	A	No	C	ND	No	No
thiophanate-methyl	E	No	D	No	B	B	ND	No	No	A	B	No	No	No	No
thiram*[1]	C	ND	C	A	B	ND	ND	ND	B	A	ND	B	No	No	Yes
trifloxystrobin	No	No	No	No	B	No	No	No	B	A	No	No	No	Yes	Yes

* chemical on the Chief Executive Initiated Reassessment (CEIR) list.

[1] these substances have also 6.3B classification

[2] O (oral), D (dermal), I (inhalation) routes

Ornamental and vegetable seedlings and bulbs

Active ingredient	Hazard Classification														
	6.1 (O) [2]	6.1 (D)	6.1 (I)	6.4	6.5	6.6	6.7	6.8	6.9	9.1	9.2	9.3	9.4	Bioaccum-ulative	Rapid biodegra-dation
quintozene	**No**	**No**	**No**	**6.4A**	**6.5B**	**ND**	**ND**	**ND**	**6.9B**	**9.1A**	**ND**	**no**	**9.4A**	**yes**	**no**
etridiazole	D	D	ND	A	No	ND	B	B	B	A	ND	C	ND	No	ND
boscalid	No	No	No	No	No	No	B	No	No	B	No	No	No	No	No
carbendazim*	E	ND	No	ND	ND	A	ND	A	B	A	B	No	No	No	No
chlorothalonil*	No	No	B	8.3A	B	No	B	No	A	A	B	B	No	No	No
copper hydroxide	D	No	ND	8.3A	B	ND	ND	ND	B	A	ND	B	ND	ND	No
fludioxonil	No	ND	ND	No	No	ND	ND	ND	B	A	No	No	No	Yes	ND
kresoxim-methyl	No	No	No	No	No	No	B	No	ND	A	No	No	C	No	No
metalaxyl-m*	D	No	No	A	B	No	No	No	B	C	No	B	No	No	No
propiconazole[1]	D	ND	ND	A	No	No	No	No	B	A	No	C	No	No	No
thiophanate-methyl	E	No	D	No	B	B	ND	No	No	A	B	No	No	No	No
thiram*[1]	C	ND	C	A	B	ND	ND	ND	B	A	ND	B	No	No	Yes
tolclofos-methyl	No	ND	D	No	ND	ND	ND	ND	B	A	ND	No	ND	Yes	No

* chemical on the Chief Executive Initiated Reassessment (CEIR) list.
[1] these substances have also 6.3B classification
[2] O (oral), D (dermal), I (inhalation) routes

Higher hazard classification compared to quintozene		**Same** hazard classification compared to quintozene		**Lower** hazard classification compared to quintozene	

5.2.8 ERMA New Zealand identified the following sources of uncertainty in performing this comparative analysis:

- Hazard assessment is not an indication of the risk posed by a substance, since exposure is not taken into account, but it can be used as an indicator of potential to cause effects.
- The concentration of active ingredient in the formulated product is also critical. It is quite possible for the hazard classification of alternative formulated products to be less than that of quintozene containing formulations even when the active ingredients are more hazardous (and vice versa) and this is not taken into account in Table 10.
- There may be other active ingredients than those considered in these alternative scenarios if quintozene was not available;
- Restricting the suite of pesticide modes of action available may lead to a reduced ability to manage pest resistance.

SECTION SIX – PROPOSALS TO MANAGE RISKS

6.1 Evaluation of risk management options

6.1.1 The results of the assessments indicate that there are non-negligible risks for both quintozene and the dioxin contaminant arising the uses of the approved quintozene containing substance. These risks, summarised in Table 11, arise from the use of the quintozene product. Additional controls that might be applied to reduce these risks are discussed.

Table 11: Summary of risks to be addressed

Area of non-negligible risk	Uses (refer to section)	Details of non-negligible risks
Ecotoxicity risks[15]		
Aquatic environment	Turf	Acute and chronic risks to fish in the freshwater environment from a single application are high. Acute risks to invertebrates from a single application are medium; however a high acute risk is seen from multiple applications. The chronic risks to invertebrates are high.
	Seedlings	Acute risks to fish are medium. Acute risk to invertebrates is low. Chronic risks to fish and invertebrates are high.
	Soil	Acute and chronic risks to fish in freshwater environment from a single application are high. Acute risks to invertebrates are medium. Chronic risks to invertebrates are high.
Ground water	Turf, Seedlings, Soil	A risk of contamination of groundwater from the use of quintozene has been identified especially on soils with low organic matter (e.g. sandy soils).
Birds	Turf, Seedlings, Soil	Chronic risks to birds were not able to be fully evaluated due to lack of data.
Terrestrials invertebrates (bees)	Turf, Seedlings, Soil	Risk to bees from single application on turf, seedlings and bulbs were not able to be fully evaluated due to lack of data.
Human health		
Operators	Turf, Seedlings, Soil, Seed boxes	Risks to the health of operators during mixing, loading, application even when full PPE is used both from quintozene and from the dioxin contaminant. While risks are lower for low use rate and frequencies (turf/tomatoes), the dioxin risks are not considered non negligible because of its persistence in the body.

[15] Note that there is no reference to use for seed boxes or bulb dipping in the ecotoxicity risk section, because, provided the user undertakes responsible handling and disposal, ecotoxicity risks from these non dispersive uses are low, and no controls to address ecotoxicity risks are needed.

Area of non-negligible risk	Uses (refer to section)	Details of non-negligible risks
	Bulbs	Risks to the health of operators during bulb dipping (and non dispersive seed treatments), and potential subsequent health risks due to contamination of equipment both from quintozene and from the dioxin contaminant. There is the potential for contamination which may result in exposure risks from dioxin long after application.
Re-entry workers	Turf, Seedlings, Soil	Risks to the health of re-entry workers from use of quintozene on turf and seed beds in the field, both from quintozene and its dioxin contaminant.
Bystanders	Turf, Seedlings, Soil	Risks to the health of bystanders are high for use of quintozene on turf and seed beds in the field due to quintozene and dioxin exposures. While risks are lower for low use rates and frequencies (turf/tomatoes), the dioxin risks are not considered negligible due because of its persistence in the body.

Additional control options to address ecotoxicity risks

6.1.2 Exposure of the aquatic environment to quintozene poses significant risks to fish and invertebrates from use on turf, seedlings and soil, through single or multiple applications, and requires additional measures to be employed to mitigate those risks. Risks to the aquatic environment could be mitigated by the use of buffer zones. A buffer zone is the distance between the downwind edge of the application area to a water body. Based on the assessment carried out by ERMA New Zealand, the buffer zone around any water body required to reduce the level of risk to acceptable, for both the use on turf (4 applications) and the use in seedlings and bulbs (pre-planting) is 200 metres or more. The model indicated that for one application on turf a buffer zone of 172 m would be required when a fine droplet size is used and 30 m would be sufficient when a coarse droplet size is used. Only for seedlings (post-planting) would no buffer zone be needed to manage ecotoxicity risks to the aquatic environment.

6.1.3 ERMA New Zealand notes that quintozene and its contaminants and degradation products are very persistent in the environment. In addition, quintozene and its contaminants and degradation products have a high potential to bioaccumulate in aquatic organisms and therefore in the food chain. It is noted the aquatic model used to identify the risk of quintozene does not take bioaccumulation and the adverse effects of the metabolites into account and therefore the risk quotients are likely to understate the ecological risk.

6.1.4 Quintozene is not likely to be very mobile in soils however ERMA New Zealand considers there is a risk of groundwater contamination especially when it is used on soils with low organic matter (e.g. sandy soils). Modelling indicates that exposure of groundwater may occur from the use of quintozene.

6.1.5 The likelihood of acute mortality to birds is considered to be low for all scenarios. The assessment of exposure of birds to quintozene has demonstrated that quintozene may pose a chronic risk to birds after just one application. The risk assessment indicates that risk reduction measures are required or further assessment is needed. ERMA New Zealand considers quintozene and its contaminants and degradation products are very persistent in the environment and display a high potential to bioaccumulate in the fatty tissue of wildlife such as birds and fish. The identified chronic risks may consequently be an underestimate. Use of physical barriers to prevent birds from entering the application area would provide a method to reduce the risk to birds. Additionally, measures would need to be taken to remove birds from the application area prior to application. However, given that such measures are impracticable and that numerous alternative substances are available and can be used without such restrictions, it may be unlikely that users would adopt the new requirements and use quintozene rather than use an alternative product. ERMA New Zealand has not been able to identify any practicable measure that could be imposed that would mitigate the identified risks to birds.

6.1.6 ERMA New Zealand's assessment has identified that quintozene poses a risk to bees. In the absence of data to allow for more detailed and specific analysis, risk reduction measures are required to reduce the risks posed to bees. The default controls that apply to application of substances that are ecotoxic to terrestrial vertebrates restrict use to periods when bees are unlikely to be foraging, reducing the risks to bees. However, quintozene would still pose a risk to other non-target invertebrates in or close to the application area. ERMA New Zealand notes that given the intended use in seedling crops and on turf, bees are not expected to be exposed to qunintozene as a result of the use of the approved substance.

6.1.7 ERMA New Zealand notes that buffer zones proposed for the protection of the aquatic environment are not protective of birds and terrestrial invertebrates that may move in and out of an application area.

Conclusion on control options to address ecotoxicity risks

6.1.8 ERMA New Zealand notes that not all of the identified risks arising from dispersive quintozene use (turf, seedlings (post-planting) and soil (pre-planting) can be reduced due to a lack of practicable options for the effects that the substance poses to the aquatic environment, birds and terrestrial invertebrates. In the absence of variations that can be applied to existing controls, or the use of additional controls, ERMA New Zealand considers that there are no practical risk management options that will reduce the risks to a negligible level. ERMA New Zealand notes that the alternative products currently available are not definitively lower in hazard, but the current level of use of quintozene as a plant protection product is very low and withdrawal of quintozene would not impact significantly on the use of these alternative products.

6.1.9 In respect to non-dispersive use (seed boxes and bulb dipping) the ecotoxicity risks during use were low (without assessment being done), but the longer term environmental contamination risk was not able to be quantitatively assessed.

Additional control options to address human health risks

6.1.10 ERMA New Zealand considers that operator exposure risks from use of quintozene, for turf and seedling uses, cannot be reduced to non-negligible levels even if full PPE is worn. The risk assessment indicates that the risks to operators from turf and seedling uses are non-negligible even where full PPE is worn, including a respirator.

6.1.11 Based on risks to operators from mixing and loading only, ERMA New Zealand considers that operator exposure risks from use of quintozene for bulb dipping are not high from this use based on the quintozene or the dioxin contaminant. However, the assessment is considered to significantly underestimate the actual risk to operators involved in bulb dipping. There may be risks from handling bulbs after treatment, particularly due to the persistent nature of dioxin residues. The approval for the substance containing quintozene does not carry a control relating to the use of gloves when handling treated seedlings or bulbs. Also the estimates do not fully take into account all exposure pathways, and do not address the persistence of the dioxin contaminant and the potential for on-going contamination issues which may lead to delayed human exposure.

6.1.12 The existing protective clothing and equipment control (Class 6, 8, 9 Regulation 8) specifies that protective clothing and equipment should be sufficient to ensure that the person does not come into contact with the substance.

6.1.13 The effectiveness of specifying PPE requirements requires that users are informed of these requirements. As such, the proposed PPE requirements should be added to product labels. Such controls would be relevant if risk management scenario (b) were to be adopted, although it would only address dioxin exposures occurring at the time of application. It would also apply in respect to risk management scenario (a), although it would not be sufficient to reduce the health risks associated with the continued use of quintozene or exposure to its dioxin contaminant so as to make them negligible.

6.1.14 Re-entry assessment indicated that the estimated exposure of re-entry workers from the use of quintozene on turf and field tomatoes is high. For turf uses, a re-entry interval of 289 days would be required before the risks associated with exposure for a re-entry operator without PPE would be negligible. Given the high risks and the long re-entry interval with the lowest transfer coefficients and the lowest application rates, ERMA New Zealand has not conducted further assessment of worker re-entry exposure. ERMA New Zealand considered the risks and re-entry intervals of all other uses would have similar outcomes. ERMA New Zealand also notes that in respect to the dioxin contaminant the possibility exists of exposure of other staff members to dioxin residues which may accumulate on equipment, preparation surfaces, and in

soil, in circumstances in which use of PPE is unlikely to be a feasible response to prevent exposures as the presence of the contamination may be unknown.

6.1.15 ERMA New Zealand has identified that bystander exposure of children adjacent to areas treated with quintozene pose a significant risk, for all the modelled application methods (turf and seed beds). The predicted buffer zones that would be needed to reduce the exposure to a level that would result in a negligible risk were greater than 100 m, with the exception of a single treatment of field tomatoes for which the application rate is the lowest. In this case, a buffer zone of 6 m would be sufficient. ERMA New Zealand also notes that in respect to the dioxin contaminant, the possibility of on-going exposure from residues from earlier applications, rather than only from recent applications must be taken into account.

6.1.16 ERMA New Zealand notes that the application of large buffer zones and long re-entry intervals are not likely to be practical for the continued use of quintozene. ERMA New Zealand expects that quintozene would often be used adjacent to residential properties and in garden stores.

6.1.17 The on-going use of quintozene, even only for non dispersive bulb/seed treatments, is likely to result in environmental contamination and could potentially generate contaminated sites if waste management is not appropriate, leading to human health and ecotoxicity risks.

6.1.18 If bulb or seed non dispersive uses are retained, it would appropriate to apply additional special controls to require that the treatment areas are cleaned after use, and that any waste and contaminated residue of the plants or soil is collected and taken off site for controlled disposal as a contaminated waste. If such controls are not put in place, such material may be disposed on site and may in later years be found to cause human or environmental damage, and unforeseen financial burden to the current or subsequent landowner.

6.1.19 The work of the Ministry for the Environment and regional councils on contaminated site issues has identified as a problem the identification of land which has been contaminated by activities undertaken many years (decades) earlier, often by previous owners (see: http://www.mfe.govt.nz/issues/hazardous/contaminated/). Land use records are of some help in identifying such contaminated areas, but they are an imprecise tool, and it can be a very costly process to identify whether or not a particular piece of land is contaminated, and if so, where on the site the contamination is located. Since quintozene and its contaminants, including dioxin, are highly persistent in the environment and there is the potential for contamination if the disposal control above is not complied with. In the event that risk management option (b) is adopted, ERMA New Zealand recommends that persons who use quintozene must inform the local regional council and the territorial authority by letter every two years indicating the quantity used and the area on the site where the use occurred. Further work is required on the need for such a requirement and the most appropriate way to implement it, if it is considered necessary.

Conclusion on additional control options to address human health risks

6.1.20 ERMA New Zealand notes that for many of the risks to operator, re-entry workers and bystanders no additional controls could be devised which would reduced the risks to the degree necessary to protect human health. Furthermore, the risk assessment has not been able to address all exposure routes and is believed to underestimate the potential long term effects from the use of quintozene, including the effects that may arise from dioxin contamination caused by even non dispersive uses.

6.1.21 If some non dispersive uses are retained, additional controls should be required and a specification for levels of hexachlorobenzene (HCB), pentachlorobenzene (QCB) and dioxin toxic equivalent concentration should be required in a specification for any product.

6.1.22 In Table 12 the proposed management measures to address risks from quintozene use where applicable are set out. In this table the additional controls that would be required for risk management scenario (a) have not been included, as this is not considered a feasible outcome of the reassessment, but some options to partially address risks are discussed for risk management scenario (b).

Table 12: Risks and proposed risk management measures

Area of effect	Uses	Level of risk (existing controls)	Proposed additional controls	Level of risk (revised controls)
Aquatic environment	Turf, Seedlings, Soil,	Non-negligible (Exceeds LOC)[16].	No practicable risk reduction options possible	Non-negligible
Birds	Turf, Seedlings, Soil,	Non-negligible (Exceeds LOC).	No practicable risk reduction options possible.	Non-negligible
Bees & other non-target invertebrates	Turf, Seedlings, Soil,	Non-negligible (Exceeds LOC)	No practicable risk reduction option to protect non-target invertebrates other than bees.	Non-negligible
Operator	Turf, Seedlings, Soil,	Non-negligible, even when full PPE is used	No practicable risk reduction option to protect operator health from turf and seed bed uses.	Non-negligible
Operator	Seed boxes, Bulbs	Not fully assessed, but considered high.	PPE could be adequate to prevent exposure at time of application. The existing PPE control should be modified to make it more prescriptive so that: Mixers/loaders must wear: • Coveralls over long-sleeved shirt and long-legged trousers; • Chemical-resistant gloves, such as barrier laminate or viton;	Potentially non-negligible

[16] LOC means Level of Concern.

Area of effect	Uses	Level of risk (existing controls)	Proposed additional controls	Level of risk (revised controls)
			• Chemical-resistant footwear plus socks; • Protective eyewear; • Chemical-resistant apron when mixing or loading; • Chemical-resistant headgear; • Respirator Applicators must wear: • Coveralls over long-sleeved shirt and long-legged trousers • Chemical-resistant gloves, such as barrier laminate or viton • Chemical-resistant footwear plus socks • Protective eyewear • Respirator PPE requirements must be identified on the product label.	
Re-entry worker	Turf, Seedlings, Soil,	Non-negligible	No practicable risk reduction option to protect the health of re-entry workers given the long re-entry intervals for higher rate uses. Introduce REI[17], where entry into treated crops is prohibited for the following time period: Tomatoes 2 days *(no REI has been able to be set for other crops due to a lack of data, though ERMA New Zealand considers that it is necessary to do so to allow safe use to operators).* Introduce PPE requirement for re-entry into treated crops (after REI, if set for crop). PPE to comprise: • Coveralls or long sleeved shirt and long trousers; • Chemical resistant gloves; • Chemical resistant footwear plus socks PPE requirements must be identified on the product label.	Non-negligible
Bystander	Turf, seeds and soil	Non-negligible	Buffer zones between the application area and bystanders.	Non-negligible

[17] REI – Restricted Entry Interval.

Area of effect	Uses	Level of risk (existing controls)	Proposed additional controls	Level of risk (revised controls)
Human health and the environment	Turf, Seedlings, Soil, Seed boxes, Bulbs,	Not assessed, but considered high.	If any quintozene uses are retained, ERMA New Zealand proposes a specification for quintozene. If risk management scenario (b) is adopted an additional control should apply to prevent use in home gardens, as the approved handler control does not prevent use in the home garden except by a contractor, and more specificially risk management scenario (b) only relates to non dispersive use for which the approved handler control is not relevant. Furthermore, ERMA New Zealand considers this is necessary to ensure illegal decanting of product to facilitate domestic use does not occur .	Potentially non-negligible
General public (essentially bystanders or future generations)	Seed boxes, Bulbs	Not assessed, but considered high.	Two additional special controls are proposed if non dispersive uses (bulb and non dispersive seed uses) are retained. Areas of use of quintozene need to be cleaned down and residue included plant material and soil or residual treatment solutions must be disposed of using a hazard waste facility. If risk management scenario (b) is adopted it is recommended that users of quintozene must inform the regional council and territorial authority by letter every two years and provide the following information: the identity of their operation and its location, the quantity of quintozene they have used, and where on their property the use occurred.	Potentially non-negligible

SECTION SEVEN – OVERALL EVALUATION

7.1 Introduction

7.1.1 In the absence of exposure information, ERMA New Zealand has used qualitative exposure assessment and quantitative exposure assessment models to determine the levels of risk to human health and the environment. This has produced indicative levels of risk that, in many cases, are high.

7.1.2 On the basis of this information, ERMA New Zealand's interim evaluation is that there are significant (non-negligible) risks associated with the use of the approved substance containing quintozene from exposure to the quintozene and its dioxin contaminant in New Zealand which outweigh the benefits. Most notably:

- risks posed to the aquatic environment;
- risks to ground water contamination;
- risks to birds;
- risks to non-target invertebrates;
- risks to operators;
- risk to re-entry workers;
- risks to bystanders (including children);
- risks to future land users and the environment from contamination.

7.1.3 ERMA New Zealand further notes that there are no practical additional controls or risk management measures that would reduce these risks to a negligible level.

7.1.4 ERMA New Zealand notes that there are likely to be some risks associated with the use of products that would likely be used as alternatives if the use of quintozene were restricted or prohibited. The majority of the alternative plant protection products have higher toxicity for class 6.1 than the quintozene, but are not contaminated with dioxin which is considered to be of greater concern than these alternative active ingredients.

7.1.5 ERMA New Zealand also notes that the level of use of quintozene is low, indicating that alternative products are predominantly being used already for the label uses of quintozene.

7.1.6 Taking these matters into account as well as the environmental properties of quintozene and its dioxin contaminant, ERMA New Zealand considers that the risks of the alternatives to quintozene are likely to be substantially lower than those from quintozene and its dioxin contaminant.

7.1.7 ERMA New Zealand has not identified any potentially significant benefits associated with the use of quintozene.

7.1.8 ERMA New Zealand notes that comparison of risks and benefits, for example, an environmental or human health risk to a societal or economic benefit requires value judgement. This is taken into account in making recommendations (Section 7.3) and the Authority will take this into account in reaching an overall assessment of the risks and benefits.

7.2 Overall Evaluation

Table 13: Summary of non-negligible risks for use of the substance containing quintozene with its dioxin contaminant

Plant Protection	Risk Management Scenario (a) (continued use with current controls)	Risk Management Scenario (b) (continued use with revised controls)	Risk Management Scenario (c) (withdrawn of all uses– reliance on alternatives)
Turf	Environmental: Non-negligible	Environmental: Non-negligible	Environmental: None
	Human Health: Non-negligible	Human Health: Non-negligible	Human Health: None
Seedlings (post planting)	Environmental: Non-negligible	Environmental: Non-negligible	Environmental: None
	Human Health: Non-negligible	Human Health: Non-negligible	Human Health: None
Soil (pre-planting)	Environmental: Non-negligible	Environmental: Non-negligible	Environmental: None
	Human Health: Non-negligible	Human Health: Non-negligible	Human Health: None
Seed boxes	Environmental: Negligible	Environmental: Negligible	Environmental: None
	Human Health: Non-negligible	Human Health: Non-negligible	Human Health: None
Bulb dipping	Environmental: Negligible	Environmental: Negligible	Environmental: None
	Human Health: Non-negligible	Human Health: Non-negligible	Human Health: None

7.2.1 ERMA New Zealand has not identified any potentially significant benefits in any areas of the assessment from the uses of the substance containing quintozene.

7.2.2 ERMA New Zealand notes that the risks associated with quintozene and its contaminants, in particular, dioxin, are greater than those of quintozene alone particularly when the persistence and bioaccumulative properties of the dioxin

are taken into account. Nevertheless the risks from quintozene alone are also non-neglible for most uses.

7.2.3 ERMA New Zealand concludes that there are non negligible risks to human health for all uses even with the additional controls, and that there are non negligible risks to the environment for all dispersive uses even with the additional controls.

7.2.4 Restriction to non dispersive uses (seed boxes and bulb dipping) appears to be consistent with North American regulatory action, but it would not be consistent with international commitments by New Zealand in respect to dioxin (and other quintozene contaminants). ERMA New Zealand also notes that areas of uncertainty make a precautionary approach appropriate.

7.2.5 ERMA New Zealand recognises that in relation to ethical considerations (see section 2.5) there is a need to consider the implications of the need for respect for people including past present and future generations. Due to the persistence of quintozene and its contaminants, in particular dioxins, the need to consider future generations is relevant.

7.2.6 ERMA New Zealand also considers revocation of all uses is appropriate taking into account international considerations specifically the Stockholm Convention (see section 4.8).

7.2.7 In preparing this application, ERMA New Zealand has not conducted a specific Māori consultation but the impression gained from hui with iwi/Māori resource managers is that unless substances provide clear benefits to outweigh potential risk, they generally oppose the ongoing use of hazardous substances. In the absence of further information regarding benefits, it is expected that submissions from Māori would seek the revocation of the approval for the substance containing quintozene with its dioxin contaminant.

7.2.8 Clauses 29 and 30 of the Methodology[18] provides that where there is scientific and technical uncertainty, the Authority must consider the materiality of the uncertainty and if it cannot be resolved to its satisfaction, the Authority must take into account the need for caution in managing the adverse effects of the substance.

7.2.9 Given the information currently before it and taking account of the need for caution, ERMA New Zealand makes the preliminary recommendations set out in Section 7.3.

7.3 Preliminary Recommendation

7.3.1 ERMA New Zealand recommends the adoption of **risk management scenario (c)** (i.e. removal of approval) for all uses of quintozene-containing substances (turf, seedlings, soil, seed boxes and bulbs), and should apply to approval HSR000742. This approval should be revoked, on the basis that:

[18] Hazardous Substances and New Organisms (Methodology) Order 1998 (SR 1998/217).

- there are risks to the environment that cannot be managed in any other way;
- numerous alternative products are available for all of the plant protection label uses;
- there is significant risk to operators posed during application and re-entry into treated crops and turf, and for bystanders from dispersive uses, generally these risk arise both from quintozene and the dioxin contaminant;
- there is uncertainty regarding the length of time taken for levels of quintozene and its dioxin contaminant to reduce to acceptable levels;
- the dioxin contaminant, contributes to the risks associated with exposure to the approved substance which are high except for the lowest use rates and frequencies, and ERMA New Zealand does not consider that risk assessment can adequately take into account the long term contamination issues that arise from use of the substance contaminated with dioxin;
- international considerations support the removal of an avoidable source of persistent organic pollutants (dioxin), which during use will be released to the environment (even from the non dispersive uses);
- it is consistent with New Zealand's commitments under the Stockholm Convention on Persistent Organic Pollutants;
- use of quintozene does not provide any significant level of benefit.

7.3.2 A question which then arises is whether a phase out period for the use of quintozene is required. ERMA New Zealand notes that the registrant has already ceased importation of the product pending the outcome of this reassessment. ERMA New Zealand proposes that a period of 6 months is permitted for holders of stock to use the product up. At this time, the substance will need to be either returned to the manufacturer or processed as a hazardous waste for environmentally sound disposal. ERMA New Zealand welcome any submissions about the feasibility of this phase out period.

7.3.3 During the period of 6 months, no modification to the current controls is proposed.

Signed_____

Chief Executive, ERMA New Zealand

Dated 28 January 2011

APPENDICES

Appendix A: Chemical and physical properties of the active ingredient and methods of analysis

Table A.1: Physico-chemical properties of the active ingredient quintozene

	Summary Information	**Reference**
Melting point / melting range	143 ^{o}C	EU footprint, quintozene
Boiling point / boiling range	328 ^{o}C	
Physical state / Appearance	Yellow crystalline solid	
Density / relative density / bulk density	1.718 g/ml	
Vapour pressure (in Pa, state temperature)	12.7 mPa at 25^{o}C	
Henry's law constant (Pa m^3 mol^{-1})	3.70 x 10	
Water solubility (g/l or mg/l, state temperature)	0.44 mg/L at 25^{o}C	US EPA 2006
	0.1 mg/L at 22^{o}C	Canada 2009
Solubility in organic solvents (in g/l or mg/l, state temperature)	At 20^{o}C Toluene: 1140 000 mg/L Methanol: 20 000 mg/L Heptane: 20 000 mg/L	EU footprint quintozene
Partition co-efficient octanol-water (log P_{OW})	Log K_{ow} = 5.1	Canada 2009
	Log P= 4.46	EU footprint quintozene
Flammability/ auto-flammability	No data	
Explodability / Explosive properties	No data	

Appendix **B: Environmental Fate of quintozene**

Table B.1: Terrestrial fate and behaviour of quintozene

	Summary Information	**Reference**
Degradation in soil		
Quintozene was found to be stable to hydrolysis and photodegradation on soil. Aerobic DT_{50} = 189 days parent only. DT_{50} = 1052 days for total residues Anaerobic DT_{50}= 30 days parent only. DT_{50} = 334 days for total residues		US EPA 2006
Soil adsorption/desorption		
Koc	4498 mg/L	EU footprint, quintozene
	1588, 2912, 3870, 17508 mg/L	US EPA 2006
Kd	7.3 , 15.5 (= lowest non-sand soil), 19.1 and 210 mg/L	
Mobility in soil		
Quintozene was found to be immobile in most soils, but has the potential to partition to organic matter in the soil and move to surface water through erosion. Therefore, the surface water was found more likely to be contaminated than groundwater.		US EPA 2006
GUS leaching potential index 0.81 which means a low leachability. (GUS = Groundwater Ubiquity Score)		EU footprint quintozene
Volatilization	Quintozene was found to be highly volatile with a vapour pressure of 12.7 mPa at 25 ^{o}C. It was determined that a significant amount of quintozene could volatilise from soil and undergo long-range transport. A photodegradation DT_{50} of 2200 days for quintozene is reported.	US EPA 2006

Table B.2: Aquatic fate and behaviour of quintozene

	Summary Information	**Reference**
Hydrolysis of active substance (DT_{50}) (State pH and temperature)	Stable at 25^{o}C and pH 5,7 and 9	US EPA 2006
Photolytic degradation of active substance	$DT_{50} \leq 2.5$ days (pH 5, 25 ^{o}C) Photodegradation is expected to be a significant route of dissipation of quintozene in the environment when the substance is present in clear shallow surface water in non-adsorbed state.	US EPA 2006

Table B.3 Fate and behaviour of quintozene in air

	Summary Information	Reference
Volatilization from soil	Quintozene was found to be highly volatile with a vapour pressure of 12.7 mPa at 25 ^{o}C. It was determined that a significant amount of quintozene could volatilise from soil and undergo long-range transport. Residues of quintozene have been detected in locations in the USA where it is not used. Based on its vapour pressure, quintozene will exist almost exclusively in the vapour phase in the atmosphere. A photodegradation DT_{50} of 2200 days for quintozene in the atmosphere is estimated.	US EPA 2006

Appendix C: Environmental Exposure Modelling

As ERMA New Zealand is unaware of locally monitored exposure concentrations, its risk assessment is based on modelling estimated environmental concentrations.

Given the persistence of quintozene and its metabolites there is a potential for long-range transport. In the US residues of quintozene have been detected in locations where quintozene is not used.

Table C.1: Scenarios used in the exposure modelling

Scenario	Crop	Equipment	Formulation	Active ingredient	Frequency/year	Interval
1	Turf	Spray: low boom + knapsack	30 kg/ha, max water amount 5000 L/ha	22.5 kg/ha	1 - 4 times, from late autumn up to early spring	30 days
2	Ornamental/vegetable seedlings and bulbs Post planting	Drench, knapsack	50 gram per 100 l water and 200 ml solution per plant (17 000 tomato plants / ha)	1.275 kg/ha (37.5 gram per 100 L water)	1 per crop	
3	Ornamental/vegetable seedlings and bulbs Pre-sowing/ planting	Spray: Low boom fine spray with incorporation to 10-15 cm	120 kg/ha	90 kg/ha	1 per crop	-

Concentrations in surface water

ERMA New Zealand has used the Generic Estimated Environmental Concentration Model v2 (GENEEC2) surface water exposure model (USEPA 2001) to estimate the expected environmental concentration (EEC) of quintozene in surface water which may potentially arise as a result of spray drift and surface runoff, following wide dispersive use.

The parameters used in the GENEEC2 modelling are listed in Table C.2.

Table C.2: Input parameters for GENEEC2 analysis

	quintozene	Reference
Application rate	See Table	
Application frequency		
Application interval		
K_d	15.5 mg/L	US EPA 2006

	quintozene	Reference
Aerobic soil DT_{50}	1052 days	
Pesticide wetted in?	No	label
Methods of application	See Table	
'No spray' zone	0	label
Water solubility	0.44 mg/L	US EPA 2006
Aerobic aquatic DT_{50}	2104 days (default 2x soil DT_{50})	
Aqueous photolysis DT_{50}	2.5 days	

The results of the modelling are summarised in Table C.3 and the model output is shown in Table C.3.

Turf, scenario 1, 1 application

RUN No. 1 FOR quintozene ON turf * INPUT VALUES *

RATE (lb/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPB)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE(FT)	INCORP (IN)
20.032(20.032)	1 1	15.5	440.0	GRLOFI(2.9)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
1052.00	2	N/A	2.50- 310.00	******	270.19

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
351.94	349.37	334.94	305.10	284.93

Turf, scenario 1, 4 applications

RUN No. 1 FOR quintozene ON turf * INPUT VALUES *

RATE (lb/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPB)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE(FT)	INCORP (IN)
20.032(77.806)	4 30	15.5	440.0	GRLOFI(2.9)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC DAYS UNTIL (FIELD)	HYDROLYSIS RAIN/RUNOFF	PHOTOLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
1052.00	2	N/A	2.50- 310.00	******	270.19

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
440.00	440.00	440.00	440.00	440.00

Ornamental and vegetable seedlings and bulbs, scenario 2

RUN No. 1 FOR quintozene ON ornamental * INPUT VALUES *

RATE (lb/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPB)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE(FT)	INCORP (IN)
1.135(1.135)	1 1	15.5	440.0	GRLOME(.8)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC DAYS UNTIL (FIELD)	HYDROLYSIS RAIN/RUNOFF	PHOTOLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
1052.00	2	N/A	2.50- 310.00	******	270.19

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
18.83	18.69	17.91	16.30	15.22

Ornamental and vegetable seedlings and bulbs, scenario 3

RUN No. 2 FOR quintozene ON seedlings * INPUT VALUES *

RATE (lb/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPB)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE(FT)	INCORP (IN)
80.128(80.128)	1 1	15.5	440.0	GRLOFI(2.9)	.0	6.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
1052.00	2	N/A	2.50- 310.00	******	270.19

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
323.53	321.52	308.74	282.15	264.14

Table C.3: Scenarios used in exposure modelling and aquatic estimated environmental concentrations for quintozene

Crop	Method		Rate	Scenario	Applications		Estimated environmental concentration (mg/l)				
	Equipment	Details	Max kg ai/ha/ application		Number per year	Interval (days)	Peak	4 day avg	21 day avg	60 day avg	90 day avg
Turf*	Low boom	Fine spray	22.5	1	1	-	0.35	0.35	0.33	0.31	0.28
					4	30	0.44	0.44	0.44	0.44	0.44
Ornamentals/ Vegetables/ bulbs Post planting	Drench (low boom)	Coarse spray	1.275	2	1	-	0.019	0.019	0.018	0.016	0.015
Ornamentals/ Vegetables/ bulbs Pre sowing/planting	Low boom + incorporation	Fine spray	90	3	1	-	0.32	0.32	0.31	0.28	0.26

* ERMA New Zealand notes that the estimated environmental concentration of 4 applications does not reduce in time. ERMA New Zealand assumes that the concentration does not reduce because of the persistency of the substance.

Concentrations in groundwater

The concentration in groundwater has been estimated using the USEPA SCIGROW model. For the use on turf the concentration is 3.4 µg/L and 13.6 µg/L for 1 and 4 applications respectively. For the seedlings and bulbs the concentration is 13.6 µg/L and 0.19 µg/L for spray application and drench application respectively.

Terrestrial exposure

Birds

The avian toxicity assessment was performed according to "Risk Assessment to Birds and Mammals (EFSA, 2008)". Full details of the methodology can be found in EFSA (2008).

The methodology calculates Toxicity Exposure Ratios (TER) where exposure is calculated as the dose that a bird will receive when feeding in crops that have been sprayed. To avoid doing detailed evaluations for low risk scenarios, assessments are performed in tiers of increasing complexity. The steps for the acute assessment are:

- Screening step
- Tier I
- Higher tier

The steps for the reproductive assessment are:

- Screening step
- Phase-specific approach
- Higher tier

Progression to the next tier is only made if the threshold for concern is exceeded at the previous tier.

Exposure

Principles

The principles underlying the exposure assessment are the same for all assessments other than higher tier assessments in which more specific field exposure data may be used. The dose that a bird receives (the DDD, Daily Dietary Dose) is calculated from the application rate and a so-called 'Shortcut value' for the RUD, Residue Unit Dose, reflecting the concentration on the bird's food and the quantity of food consumed. Quantities consumed are based on a bird's energy requirements, its energy assimilation, and the energy content of its food (dry weight). Birds' energy requirements are based on an algorithm based on bodyweight and bird type (e.g. passerine/non-passerine). The parameters used to calculate a bird's exposure are summarised in Table C.4.

Table C.4: Parameters used for estimating bird Daily Dietary Dose

<table>
<tr><td rowspan="2">Application rate$_{multiple\text{-}applications}$</td><td colspan="3">Application rate$_{single\text{-}application}$</td></tr>
<tr><td colspan="3">Multiple Application Factor (MAF)
(90th percentile residue based on DT$_{50(foliage)}$ = 10 days)</td></tr>
<tr><td rowspan="5">Shortcut value for Residue Unit Dose, (RUD)</td><td rowspan="4">Food intake rate</td><td rowspan="2">Daily energy expenditure</td><td>Body weight</td></tr>
<tr><td>Bird type</td></tr>
<tr><td colspan="2">Energy in food</td></tr>
<tr><td colspan="2">Energy assimilation efficiency</td></tr>
<tr><td colspan="2">Moisture content of food</td></tr>
<tr><td colspan="3">Concentration in/on fresh diet</td></tr>
</table>

Screening step exposure

Both screening step assessments (acute and reproduction) select from 6 'indicator species' each applicable to a particular type of crop. They are not real species, but, by virtue of their size and feeding habits, their exposure is considered worst-case for birds in a particular crop type. For example, the representative species for grassland is described as a 'large herbivorous bird'. It is assumed that the relevant indicator species feeds only on contaminated food and the concentration of pesticide on the food is not affected by the growth stage of the crop. Thus, the exposure assessment is expressed as:

$$DDD_{multiple\text{-}applications} = \text{Application rate x MAF x shortcut value}$$

Where:

- MAF is chosen from a table based on number of applications and interval between applications. For an acute screening assessment, the MAF_{90} is used, for a reproductive assessment the MAF_{mean} is used;
- Shortcut value is chosen from a table containing 6 crop types with a shortcut value (90th percentile and mean) for each.

Exposure in Tier I acute and Phase-specific reproduction assessments

In the Tier I acute and Phase-specific reproduction assessments exposure is calculated for generic focal species', applicable to particular crops. Such assessments refine the screening step assessments in that:

- there are more bird 'species' (19) and crop options (21);
- the growth stage of the crop is taken into account, affecting the residues on the feed;
- more than one bird species may be considered for any one crop;
- a bird's diet can be calculated to include more than one food item.

The larger number of bird species, crop types and growth stages of the crops leads to a total of 138 RUD shortcut options, each with a mean and 90th percentile value.

The exposure assessment of the Phase-specific reproduction assessment uses time-weighted average (TWA) exposure estimates over 1, 2, 3 or 21 days for different phases of the assessment. To estimate these average concentrations, the initial exposure estimates (DDD) are multiplied by TWA factors of:

Exposure	TWA factor
1 day	1.0
2 days	0.93
3 days	0.9
21 days	0.53

Higher tier

In higher tier assessments, both acute and reproduction, additional factors affecting exposure may be taken into account. These include the proportion of a bird's diet obtained in treated areas and measured residue levels. These higher tier refinements will be substance specific and are not discussed further here.

Exposure to quintozene

The exposure of birds to quintozene is shown in Tables C.5 and C.6.

Table C.5: Exposure of birds for acute assessment

Assessment / scenario	Crop & BBCH class (where appropriate)[1]	Indicator/generic Species[2]	90th percentile short-cut value[3]	Application rate (kg ai /ha)	MAF (90th %)[4]	$DDD_{multiple\ applications}$
Screening/ 1	Turf 1x	Large herbivorous bird	50.3	22.5	1	1 132
	Turf 4x				1.3	1 471
Screening/ 2	Seedlings and bulbs Post planting	Small insectivorous bird	46.8	1.275	1	59.67
Screening/ 3	Seedlings and bulbs Pre sowing/planting (bare soil)	Small granivorous bird	24.7	90	1	2 223
First tier/ 1	Turf 1x	Small granivorous bird, sparrow	20.4	22.5	1	459
		Small granivorous bird, finch	24.7	22.5	1	558
		Large herbivorous bird, goose	50.3	22.5	1	1132
		Small insectivorous bird, wagtail	26.8	22.5	1	603
First tier/ 1	Turf 4x	Small granivorous bird, sparrow	20.4	22.5	1.3	597
		Small granivorous bird, finch	24.7	22.5	1.3	722
		Large herbivorous bird, goose	50.3	22.5	1.3	1471
		Small insectivorous bird, wagtail	26.8	22.5	1.3	784
First tier/ 2	Seedlings and bulbs	Small insectivorous/worm	7.4	1.275	1	9.44

Assessment / scenario	Crop & BBCH class (where appropriate)[1]	Indicator/generic Species[2]	90th percentile short-cut value[3]	Application rate (kg ai /ha)	MAF (90th %)[4]	$DDD_{multiple\ applications}$
	Post planting	feeding species, thrush				
First tier/ 3	Seedlings and bulbs Pre sowing/ planting (bare soil)	Small granivorous bird, finch	24.7	90	1	2223
		Small omnivorous bird, lark	17.4	90	1	1566
		Small insectivorous bird, wagtail	10.9	90	1	981

[1] Crop type (EFSA, 2008, Table I.1 & I.3)

[2] Indicator species (EFSA, 2008, Table I.1 & I.3)

[3] Short-cut value (EFSA, 2008, Table I.1 & I.3)

[4] Multiple application factor (90th percentile) (EFSA, 2008, Table 11)

Table C.6: Exposure of birds for reproduction assessment

Assessment/ scenario	Crop[1]	Generic focal species[2]	Mean short-cut value[3]	Application rate (kg ai/ha)	MAF (mean)[4]	TWA $DDD_{multiple\ applications}$			
						1 day	2 days	3 days	21 days
Screening/1	Turf 1x	Large herbivorous bird	26.7	22.5	1	601	559	541	319
	Turf 4x				1.6	961	894	865	509
Screening / 2	Seedlings and bulbs Post planting	Small insectivorous bird	18.2	1.275	1	23.21	21.58	20.89	12.30
Screening/ 3	Seedlings and bulbs Pre sowing/ planting	Small granivorous bird	11.4	90	1	1026	954	923	544

[1] Crop type (EFSA, 2008, Tables I.1 & I.3)

[2] Generic focal species (EFSA, 2008, Tables I.1 & I.3)

[3] Short-cut value (EFSA, 2008, Tables I.1 & I.3)

[4] Multiple application factor (mean) (EFSA, 2008, Table 14)

Bees

The risk assessment was performed according the European model [Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC, SANCO/ 10329/2002 rev. 2 final, 17 October 2002]. The application rate is used as an indicator of exposure.

Soil organisms, plants and terrestrial invertebrate (other than bees)

No toxicity data on earthworm, plants and terrestrial invertebrates (other than bees) are available. Therefore ERMA NZ did not make an exposure assessment for those species.

Appendix D: Ecotoxicity of quintozene

Table D.1: Aquatic toxicity

	Species and life stage tested	Test substance and concentrations tested	Test method	Observations and results	Reference
Acute toxicity fish	Bluegill Sunfish *Lepomis macrochirus*	quintozene	96 h, flow through	LC_{50} =0.1 mg/L	US EPA 2006
Long term toxicity fish (early life stage)	Rainbow trout *Oncorhynchus mykiss*	quintozene	95 d	NOEL= 0.013 mg/L (affected length and weight)	US EPA PEST
Acute toxicity invertebrate	*Daphnia magna*	quintozene	48 h	EC_{50} = 0.77 mg/L	US EPA 2006
	Oyster *Crassostrea virginica*	quintozene	96 h	LC_{50} =0.023 mg/L	US EPA 2006
	Shrimp *Mysidopsis bahia*	quintozene	96 h	LC_{50} =0.012 mg/L	US EPA 2006
Long-term toxicity invertebrate (reproduction)	*Daphnia magna*	quintozene	21 d	NOEL= 0.018 mg/L	US EPA National Information Centre, quintozene
Toxicity to algae	No data				
Toxicity to aquatic vascular plants	No data				
Acute toxicity sediment-dwelling organisms	No data				
Chronic toxicity sediment-dwelling organisms	No data				
Activated sludge	No data				

Table D.2: Bioconcentration of quintozene

Bioconcentration	
Bioconcentration factor (BCF) based on study whole fish= 1100	US EPA 2006

Table D.3: Toxicity to terrestrial vertebrates

	Species and life stage tested	**Test substance and doses/concentrations tested**	**Test method**	**Observations and results**	**Reference**
Acute oral toxicity to mammals	-	quintozene		LD_{50} >5050 mg/kg bw	US EPA RED 2006
Acute dermal toxicity to mammals	-	quintozene		LD_{50} > 5000 mg/kg	US EPA 2006
Acute oral toxicity to birds	Bobwhite quail	quintozene	14 d	LD_{50}> 2250 mg/kg bw	US EPA Pesticide ecotoxicity database
Dietary toxicity to birds	Northern bobwhite quail and mallard duck	quintozene		NOEC =600 ppm	US EPA 2006

Table D.4: Toxicity to terrestrial invertebrates

Effects on honeybees					
	Species and life stage tested	**Test substance and doses/concentrations tested**	**Test method**	**Observations and results**	**Reference**
Acute oral toxicity	Honey bee	No data			
Acute contact toxicity	Honey bee	quintozene	Acute contact, 48 h	LD_{50}= 0.1 µg/bee	US EPA National Information Centre, quintozene

No data are available on earthworm, other soil organisms or terrestrial plants.

Environmental classification

On the basis of these ecotoxicity data, quintozene was classified for environmental endpoints.

Table D.5: Environmental Classification of quintozene

Hazard Class/Subclass	Hazard classification	Method of classification	Reference for source data
Subclass 9.1	9.1A	Fish LC_{50}= 0.1 mg/L Crustacea *Dapnia magna* EC_{50}= 0.77 mg/L *Shrimp* LC_{50}= 0.012 mg/L Algae no data	US EPA 2006
Subclass 9.2	No data		
Subclass 9.3	no	Rat LD_{50} > 5000 mg/kg bw Bird LD_{50} > 2250 mg/kg bw	Quintozene - Pesticide residues in food: 1995 evaluations Part II Toxicological & Environmental [INCHEM] US EPA 2006
Subclass 9.4	9.4A	Bee $LD_{50\ contact}$= 0.1 µg/bee	US EPA National Information Centre, quintozene

Appendix E: Risk Assessment: Environment

Introduction

An estimation of environmental risks has been made on the basis of available information on the use of quintozene using standard modelling tools to estimate exposure concentrations in combination with the data on the ecotoxicity of the substance.

Aquatic organisms

For Class 9 substances, irrespective of the intrinsic hazard classification, the ecological risk can be assessed for a substance or its components by calculating a risk quotient (RQ) based on measured or estimated exposure concentrations. Estimated exposure concentrations (EEC) are calculated taking into account use scenarios (including spray drift, application rates and frequencies), and the fate of the product including half-lives of the substance and its metabolites in soil and water. Dividing an EEC by the LC_{50} or EC_{50} generates an acute RQ whilst dividing the EEC by the NOEC generates a chronic RQ as follows:

$$\text{Acute RQ} = \frac{\text{EEC}}{LC_{50} \text{ or } EC_{50}} \qquad \text{Chronic RQ} = \frac{\text{EEC}}{\text{NOEC}}$$

If the RQ exceeds a predefined level of concern (see below), it may be appropriate to refine the risk assessment or apply controls to ensure that appropriate matters are taken into account to minimise off-site movement of the substance. Conversely, if a worst-case scenario is used, and the level of concern is not exceeded, then in terms of the environment, there is a presumption of low risk which is able to be adequately managed by existing controls.

Levels of concern (LOC) developed by the USEPA (Urban & Cook, 1986), and adopted by ERMA New Zealand, to determine whether a substance poses an environmental risk are shown in Table E.1.

Table E.1: Levels of concern in environmental risk assessment for aquatic and organisms

	Level of Concern (LOC)	**Presumption**
Fish and invertebrates		
Acute RQ	≥0.5	High acute risk
	0.1–0.5	Risk can be mitigated through restricted use
	<0.1	Low acute risk
Plants		
Acute RQ	≥1	High acute risk

Terrestrial organisms

For terrestrial organisms toxicity-exposure ratios (TER) are used for terrestrial vertebrates and hazard quotient (HQ) values for terrestrial invertebrates. This convention results in concern arising if a risk quotient is less than the trigger value for birds and more than a trigger value for terrestrial invertebrates.

Birds

The avian toxicity assessment was performed according to "Risk Assessment to Birds and Mammals (EFSA 2008)". Full details of the methodology can be found in EFSA (2008).

Acute assessments

In both the screening and Tier I assessments, exposure estimates are compared to the LD_{50} from an oral toxicity study[19]:

$$TER = LD_{50}/DDD$$

Interpretation of the TER is based on thresholds for concern:

TER ≥ 10	no refinement required
TER < 10	proceed to next tier assessment

Reproduction

In the screening assessment, exposure estimates are compared to the lowest NOAEL from an avian reproduction study. 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. The TER is:

$$TER = NOAEL/DDD$$

And the thresholds for concern are:

TER ≥ 5	no refinement required
TER < 5	proceed to phase-specific assessment

In the phase-specific assessment, risk estimates are made for all phases of reproduction using the measures of toxicity and exposure shown in Table E.2 and TER are evaluated as shown in Table E.3.

[19] If data are only available from a dietary study these can be used with appropriate conversion to dose/unit bodyweight.

Table E.2: Measures of exposure and toxicity used in the reproduction assessment

Breeding phase	Test endpoint used as surrogate	Short-term exposure	Long-term exposure
Pair formation/ breeding site selection	0.1 x LD_{50}[20]	1 day DDD	21 day TWA DDD
Copulation and egg laying (5 days pre-laying through end of laying	NOAEL for the number of eggs laid per hen	1 day DDD	21 day TWA DDD
	NOAEL for mean eggshell thickness	1 day DDD	21 day TWA DDD
Incubation and hatching	0.1 x LD_{50}	1 day DDD	21 day TWA DDD
	NOAEL for proportion of viable eggs/eggs set/hen	1 day DDD	21 day TWA DDD
	NOAEL for proportion of hatchlings/viable eggs/hen	3 day TWA DDD	21 day TWA DDD
Juvenile growth and survival until fledging	0.1 x LD_{50} (extrinsic adult)	2 day TWA DDD	21 day TWA DDD
	0.1 x LD_{50} (extrinsic juvenile)	1 day DDD based on chick shortcut values of 3.8 and 22.7[21]	21 day TWA DDD based on chick shortcut value of 3.8 and 22.7[21]
	NOAEL for proportion of 14 day old juveniles/number of hatchlings/hen	3 day TWA DDD	21 day TWA DDD
Post-fledging survival	0.1 x LD_{50}	1 day DDD based on chick shortcut values of 3.8 and 22.7[21]	21 day TWA DDD based on chick shortcut value of 3.8 and 22.7[21]
	NOAEL for 14 day old juvenile weights/hen	3 day TWA DDD	21 day TWA DDD

Table E.3: Interpretation of TER in reproduction phase-specific assessment

Assessment outcome		
Short-term exposure (1-3 day)	Long-term exposure (21 day)	**Next Steps**
TER ≥ 5	TER ≥ 5	No refinement required
TER<5	TER ≥ 5	Further refinement is required. One possibility is to determine if the effects are the result of short-term exposure
TER<5	TER<5	Further refinement is required. Refinement should focus on refining exposure and the consequences of effects. Little will be gained from additional effects data.

[20] From acute study

[21] The two values are to account for ground and foliar dwelling arthropods with mean residue unit doses of 3.5 and 21 respectively. Assessments are made with both values. If TER are exceeded with either value, then an assessment based on the actual composition of the diet of relevant species.

Bees

The following European model has been adopted by ERMA New Zealand to assess the risk to bees [EU Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC, SANCO/ 10329/2002 rev. 2 final, 17 October 2002].

Hazard Quotient (HQ) = Application Rate / LD_{50}

Application rate: the maximum single application rate (g active ingredient/ha).

LD_{50}: µg active ingredient/bee.

Risk assessment

Aquatic organisms

Acute risks to aquatic organisms are shown in Table E.4.

Table E.4: Environmental risk quotients for aquatic organisms

Compartment	Exposure duration	Expected Environmental concentration (mg/L)				Receptor	Effect concentra-tion (mg/L)	Risk Quotient			
		Scenario 1 (1x)	Scenario 1 (4x)	Scenario 2	Scenario 3			Scenario 1 (1x)	Scenario 1 (4x)	Scenario 2	Scenario 3
Freshwater	Acute	0.35	0.44	0.019	0.32	Fish	0.1	3.5	4.4	0.19	3.2
						Invertebrates	0.77	0.45	0.57	0.02	0.42
	Chronic (90 days)	0.28	0.44	0.015	0.26	Fish	0.013	21.54	33.85	1.15	20
	Chronic (21 days)	0.33	0.44	0.018	0.31	Invertebrates	0.018	18.33	24.44	1	17.22
Marine water	acute	0.35	0.44	0.019	0.32	invertebrates	0.012	29.17	36.67	1.58	26.67

Scenarios

1 Turf, 1 and 4 applications, 22.5 kg ai/ha

2 Ornamental/vegetable seedling and bulbs, 1 application, 90 kg ai /ha

3 Ornamental/vegetable seedlings and bulbs, post planting, 1 application, 1.275 kg ai/ha

Comparison of levels of concern (Table E.1) to the risk quotient in Table E.3 shows high acute and chronic risks to fish in the freshwater environment for use scenarios 1 and 3. The acute risks to fish can be mitigated through restricted use for scenario 2 but the chronic risks are high. The acute risks to invertebrates in the fresh water environment can be mitigated by restricted use when the product is used once for the scenarios 1 and 3 but the risks are high when it is applied 4 times. The risks can be mitigated for example by the implementation of buffer zones. The acute risk to invertebrates with the lowest application rate (scenario 2) is low. The chronic risks to invertebrates are high. In salt water the acute risks for invertebrates are high. Due to a lack of data on aquatic plants no risk assessment for these species could be made. This conclusion is based on Tier 0 modelling of exposure (GENEEC2).

To explore risk reduction options, ERMA New Zealand used the AgDrift model to estimate the buffer zone that would reduce exposure through spray drift to a concentration unlikely to cause acute toxicity. The receiving water was defined as a 30 cm deep pond. Spray drift is only one route of exposure by which quintozene will contaminate the aquatic environment, runoff of sorbed residues is also expected to occur, but this has not been modelled due to lack of a suitable higher tier model available to ERMA New Zealand. The AgDrift model indicated that for both the use on turf (4x) and the use in seedlings and bulbs (pre-planting), a buffer zone of 200 meters or more is required to reduce the receiving water concentration to less than the lowest acute EC/LC_{50} irrespective of the droplet size. The model indicated that for one application on turf a buffer zone of 172 m is required when a fine droplet size is used and 30 m will be sufficient when a coarse droplet size is used. The drench application in ornamental/vegetable seedlings (post-planting) requires a buffer zone of 2 m with a fine droplet size and 0.25 m with a coarse droplet size.

Impurities and degradation products

One of the contaminants in quintozene is the dioxin TEQ (The toxic equivalent concentration of 2,3,7,8-TCDD represents the combined polychlorinated dibenzo para dioxin and dibenzofuran congeners in the mixture). The acute toxicity of this substance (2,3,7,8 TCDD) to fish is LC_{50}= 1.8 mg/L which is less toxic acutely compared to quintozene. Another impurity which is also a degradation product of quintozene is hexachlorobenzene (HCB). The acute toxicity of HCB is: fish LC_{50} = 0.12 mg/L, invertebrates $EC_{50\ (24\ h)}$< 0.03 mg/L, alga EC_{50}< 0.03 mg/L. The chronic values are NOEC=0.005 mg/L, LOEC= 0.00013 mg/L and NOEC= 0.018 mg/L respectively. The acute values are comparable with those of quintozene but the concentrations causing chronic effects are lower. HCB is very persistent in soils (DT_{50} 3-6 years) and has a DT_{50} in the aquatic environment of approximately 5 years.

ERMA New Zealand notes that quintozene and its impurities and degradation products are found to be very persistent in the environment. Given this persistence and the relative toxicity of HCB compared to quintozene, aquatic risks may persist for a considerable period (years) and will only significantly reduce due to dilution. In addition, quintozene has a high potential to accumulate in aquatic organisms and therefore in the food chain. The aquatic model used to identify the risk of quintozene does not take bioaccumulation and the adverse effects of the metabolites into account therefore the risk quotients understate the ecological risk.

Groundwater

Tier 0 modelling of concentrations in groundwater predicts a concentration of 0.19, 3.4 and 13.6 µg/L depending on the use. In the EU 0.1 µg/L is the concentration above which the predicted concentration is considered to be unacceptable. Although quintozene is not likely to be very mobile in most soils ERMA New Zealand considers there is a risk for contamination of groundwater especially on soils with low organic matter (e.g. sandy soils).

Terrestrial organisms

Birds

The toxicity values used in the risk assessment of quintozene are shown in Table E.5.

Table E.5: Toxicity values used in risk assessment

Endpoint	Value (mg/kg bw/d)	Study	Reference
LD_{50}	> 2250	Acute oral, 14 d	US EPA PEST
$NOAEL_{number\ of\ eggs\ laid/hen}$	-		
$NOAEL_{mean\ egg\ shell\ thickness}$	-		
$NOAEL_{proportion\ of\ viable\ eggs\ set/hen}$	-		
$NOAEL_{\ proportion\ of\ hatchling\ per\ viable\ eggs/hen}$	-		
$NOAEL_{\ proportion\ of\ 14\ day\ old\ juveniles\ per\ number\ of\ hatchlings/hen}$	-		
$NOAEL_{14\ day\ juvenile\ weights/hen}$	-		
$NOAEL_{lowest}$	600 ppm = 60 mg/kg bw/d		US EPA 2006

The results of the risk assessment are shown in Table E.6 (acute risk) and Table E.7 (risks to reproduction).

It is concluded:

Acute risks

Given the results of the screening step and first tier assessment, higher tier risk assessment is necessary to refine the risk assessment or risk mitigation measures are required for scenarios 1 and 3. No refinement is necessary for scenario 2. However, the LD_{50} value used in the risk assessment was greater than the highest concentration tested. Therefore all acute toxicity-exposure ratios (TER) are more than the calculated value. Hence, ERMA New Zealand considers the likelihood of acute mortality to birds to be low for all use scenarios.

Chronic risks

Given the results of the screening step, quintozene may pose a chronic risk to birds after just one application. The risk assessment triggers a need for refinement of this tier 1 assessment or risk mitigation measures. However, the original study is not available therefore ERMA New Zealand is not able to refine the risk assessment.

Impurities and degradation products

No information on the toxicity to birds of the impurity 2,3,7,8-TCDD (to reflect the dioxin TEQ) is available. The toxicity of hexachlorobenzene to birds is LD_{50} = 617 ppm and the chronic LOAEL = 20 ppm. This means that this substance is more toxic to birds than quintozene itself.

Besides the toxicity ERMA New Zealand notes that quintozene and its impurities and degradation products are found to be very persistent in the environment and display a high potential to accumulate in fatty tissue of wildlife, such as birds and (shell) fish. Biomagnification is therefore possible. ERMA New Zealand considers the identified environmental chronic risks from the use of quintozene to be an underestimation of the risk.

Table E.6: Acute risks to birds from exposure to quintozene

Crop[1]	Indicator Species[2]	Assessment		TER[3]		Conclusion
Turf	Large herbivorous bird	Screening	1x	LD_{50}/DDD_{ma}	>1.9	Acute Tier I assessment triggered
			4x		>1.5	
	Small granivorous bird, sparrow	First tier	New sown 1x	LD_{50}/DDD_{ma}	>4.9	Further refinement required, or risk mitigation. No data available to refine the risk estimates.
			New sown 4x		>3.8	
	Small granivorous bird, finch		Late season 1x	LD_{50}/DDD_{ma}	>4.0	
			Late season 4x		>3.1	
	Large herbivorous bird, goose		Growing shoots 1x	LD_{50}/DDD_{ma}	>1.9	
					>1.5	
	Small insectivorous bird, wagtail		Growing shoots 4x	LD_{50}/DDD_{ma}	>3.7	
					>2.9	
Seedlings and bulbs Pre sowing/ planting	Small granivorous bird,	Screening		LD_{50}/DDD_{ma}	>1.0	Acute Tier I assessment triggered
	Small granivorous bird, finch	First tier		LD_{50}/DDD_{ma}	>1.0	Further refinement required, or risk mitigation. No data available to refine the risk estimates.
	Small omnivorous bird, lark			LD_{50}/DDD_{ma}	>1.4	
	Small insectivorous bird, wagtail			LD_{50}/DDD_{ma}	>2.3	

Crop[1]	Indicator Species[2]	Assessment		TER[3]		Conclusion
Seedlings and bulbs Post planting	Small insectivorous bird	screening		LD_{50}/DDD_{ma}	>37.7	No further refinement needed

[1] Crop type Table I.1 (Annex 1) and Appendix 10

[2] Species type Table I.1 (Annex 1) and Appendix 10

[3] Toxicity-exposure ratio = LD_{50} / Estimated environmental concentration

Table E.7: Risks to bird reproduction from exposure to quintozene

Breeding phase	Test endpoint used as surrogate	TER		Conclusion
		Short-term exposure	Long-term exposure	
Reproduction, screening for scenarios 1 and 3	Lowest NOAEL from reproduction study	Turf 1x 0.10 Turf 4x and seedlings 0.06		Phase-specific assessment triggered. No data available to refine the risk estimates.
Reproduction, screening for scenario 2		2.59		

Bees

The terrestrial invertebrate risk assessment for agricultural pesticides determines whether or not the proposed application poses an unacceptable risk to terrestrial invertebrates (bees).

The following European model has been adopted by ERMA New Zealand to assess the risk to bees [Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC, SANCO/ 10329/2002 rev. 2 final, 17 October 2002].

Hazard Quotient (HQ) = Application Rate / LD_{50}

Application rate: the maximum single application rate (g active ingredient/ha).

LD_{50}: µg active ingredient/bee.

Turf
HQ= 22 500/ 0.1= 225 000

Seedlings, bulbs: pre-sowing/planting
HQ= 90 000/0.1 = 900 000

Seedlings, bulbs: post planting
HQ = 1275 / 0.1 = 12750

These HQ greatly exceed the critical HQ of 50. HQ values that exceed levels of concern may be refined using the results of higher tier testing such as a semi-field and field trials. No data from higher tier testing were available to ERMA New Zealand.

Other terrestrial organisms

Due to a lack of toxicity data on earthworm, plants and terrestrial invertebrates (other than bees) ERMA New Zealand was not able to perform a risk assessment for those species.

Bulb dipping

ERMA New Zealand did not assess the risks to the environment of bulb dipping because there is insufficient information on practices followed. However, ERMA New Zealand has concerns that surplus solution will be disposed of over ground and/or via waste water drains. Given the properties of the substance ERMA New Zealand proposes strict controls around the disposal of used or surplus solutions.

Long-range transport

Environmental fate properties of quintozene demonstrate potential for long-range transport.

Monitoring data from US show that residues of quintozene have been detected in locations where it is not used. Therefore the effects of quintozene may not be limited to organisms in close proximity to quintozene use. As exposure models do not take into account long-range transport, ERMA New Zealand considers the identified risks of quintozene to be an underestimation of the risk.

Conclusions environmental risks

ERMA New Zealand concludes that levels of concern are exceeded for fish and aquatic invertebrates (acute and chronic), birds (chronic) and bees (acute) for most use scenarios. Only one application with the lowest dose rate (scenario 2) does not exceed the level of concern of acute risks to aquatic invertebrates. Higher tier modelling could potentially refine these estimated of the risks but is unlikely to reduce the risk quotients by the orders of magnitude required to remove the estimation of risks. Therefore risk mitigation measures need to be considered.

Furthermore ERMA New Zealand notes that quintozene and its impurities and degradation products are found to be very persistent in the environment and display a high potential to accumulate in fatty tissue of wildlife, such as birds and (shell) fish. Therefore ERMA New Zealand considers the identified risks of quintozene an underestimation.

Also the potential for long-range transport of quintozene contributes to environmental risks which are not taken into account by modelling risk quotients.

Although quintozene is not likely to be very mobile in most soils ERMA New Zealand considers there is a risk for contamination of groundwater especially on soils with low organic matter (e.g. sandy soils).

For the aquatic environment, risks can be mitigated by the use of buffer zones. Assessment of spray drift deposition indicates that the size of such buffer zones is affected by application equipment and application rate and frequency. A buffer zone of 200 m or more is required for multiple applications on turf and the pre-planting application in ornamental/vegetable seedlings and bulbs. A 30 meter buffer zone will be sufficient to protect the aquatic environment after one application with a coarse droplet size on turf. Only the drench application in ornamentals (scenario 2) requires a buffer zone that can be neglected (0.25 m).

Buffer zones are not protective of birds and bees that may move in and out of a crop. Given the intended use in seedling crops and on turf exposure to bees is not very likely. Nevertheless, timing of application to avoid times bees are foraging will reduce any risk there may be for bees.

To protect the environment other mitigation measures may be:

- Restrict the use in ornamental and vegetable seedlings to indoor use only, with additional controls regarding disposal of surplus or used solutions;
- Restrict the use in flower bulbs to dip treatment only, with additional controls regarding disposal of surplus or used solutions;
- Restrict the use on turf to spot treatment with a maximum frequency of one per year and with a buffer zone of 30 m to water ways and a requirement to use coarse droplets.

Appendix F: Classification of Quintozene (Class 6), Derivation of AOEL for Quintozene and the Tolerable Monthly Intake of Dioxin

F1 Quintozene

F1.1 Classification of Quintozene

Since the purpose of this reassessment is primarily to assess the health and environmental risk presented by the dioxin content of quintozene, ERMA New Zealand has not extensively reviewed the data available relating to the quintozene technical active ingredient or the formulated product, approved as "Water dispersible granule or wettable powder containing 750 g/kg quintozene". Nevertheless, readily available information relating to quintozene has been reviewed and the hazard classifications reviewed.

The current class 6 classifications of technical grade quintozene are:

Description	Classification
Eye irritant	6.4A
Contact sensitiser	6.5B
Target organ systemic toxicant from repeat oral exposure	6.9B

There is no HSNO approval for quintozene itself in the HSNO Chemicals Transfer Notice 2006, as the substance was not known to be in New Zealand apart from in formulated products. The only HSNO approval relating to quintozene is for the permitted substance description above "Water dispersible granule or wettable powder containing 750 g/kg quintozene", the classification of which was based on the quintozene classification above.

F1.2 US EPA RED (2005)

The key toxicological end points for quintozene adapted from the US EPA RED document for PCNB (pentachloronitrobenzene)[22] are listed in Table F.1.

[22] Some overseas sources (e.g. US EPA) use a synonym, pentachloronitrobenzene, PCNB, as the common name for quintozene.

Table F.1: Summary of Key Information for Toxicological Endpoints for Quintozene derived from the US EPA RED (US EPA, 2006)

Hazardous Property	ERMA New Zealand's Current Classification	Overseas Classification	Key information	Agency comment
Acute Toxicity (Oral)	No	US EPA Category IV	**LD_{50} = >5050 mg/kg** AMVAC data MRID No 41443101 Guideline No: 81-1/ 870.1100 Acute Oral	None
Acute Toxicity (Dermal)	No	US EPA Category III US EPA Category IV	LD_{50} = > 2020 mg/kg (AMVAC data) MRID No 41443102 Guideline No: 81-2/ 870.1200 Acute Dermal **LD_{50} = > 5000 mg/kg** (Chemutura data) MRID No 43198202 Guideline No: 81-2/ 870.1200 Acute Dermal	None
Acute Toxicity (Inhalation)	No	US EPA Category III	**LC_{50} = > 6.49 mg/L** AMVAC data MRID No 41443103	None
Skin Irritancy/Corrosivity	No	US EPA Category IV	PPI (Primary irritation index) 0.0175 (AMVAC data) MRID No 41443105 Guideline No: 81-2/ 870.2500 Primary Eye Irritation	None
Eye Irritancy/Corrosivity	6.4A	US EPA Category III	Slight irritant (AMVAC data) MRID No 41443109 Guideline No: 81-2/ 870.2400 Primary Eye Irritation	None
Respiratory Sensitisation	ND[#]	No information		None
Contact Sensitisation	6.5B		Non sensitiser (AMVAC) Weak sensitiser (Chemtura)	None

Hazardous Property	ERMA New Zealand's Current Classification	Overseas Classification	Key information	Agency comment
Mutagenicity	No	No information		None
Carcinogenicity	ND	Group C (possible human carcinogen)	PCNB is classified as a Group C (possible human) carcinogen. Chronic/Oncogenicity Study (rat) LOAEL = 150 mg/kg/day based on hepatocellular hypertrophy and hyperplasia, thyroid hypertrophy.	See discussion below
Reproductive/ Developmental Toxicity	None	No information		See discussion below
Specific Target Organ Toxicity Single Dose	None	No information		None
Specific Target Organ Toxicity Repeated Exposure (Oral)	6.9B (oral)	NA#	90-Day Subchronic (rat) LOAEL = 1.0 mg/kg/day based on threshold effects (liver and thyroid lesions) seen at lowest dose tested Acute Dermal	See discussion below
Specific Target Organ Toxicity Repeated Exposure (Dermal)	ND (dermal)	NA	21-Day Dermal (rat) LOAEL = 1000 mg/kg/day based on hypertrophy of the thyroid follicular epithelium and dilation of the thyroid follicles in males Chronic/Oncogenicity Study (rat) LOAEL = 150 mg/kg/day based on hepatocellular hypertrophy and hyperplasia, thyroid hypertrophy	See discussion below
Specific Target Organ Toxicity Repeated Exposure (Inhalation)	ND (inhalation)	No information		No change

* ND = No Data

\# NA = Not applicable

For end points for which the data in the US EPA RED document includes studies carried out on technical grade material from AMVAC (which applies primarily for the short term studies), these data are assumed to be relevant to the formulation on the New Zealand market.

F1.3 Agency review

ERMA New Zealand notes that the database for quintozene indicates that the technical grade active ingredient has, over several decades of use, contained a number of toxicologically significant impurities which are discussed below.

The key classifications which ERMA New Zealand reviewed further were carcinogenicity (6.7), reproductive/developmental toxicity (6.8) and target organ systemic toxicity (6.9). ERMA New Zealand has summarised its review for these end points below.

F1.3.1 Purity of the technical grade active ingredient quintozene

Apart from the dioxin contaminant which is the primary reason for this reassessment, and which is discussed in detail in a separate section below, ERMA New Zealand notes that the JMPR review (WHO, 1995) and other sources (IPCS, 1989) indicate that technical grade quintozene contained at least two toxicologically significant impurities, hexachlorobenzene (HCB) and pentachlorobenzene (QCB). JMPR indicates that some toxicological studies used technical grade active ingredient containing concentrations as high as 2.7% HCB. The JMPR review indicates that the HCB impurity is more persistent and bioaccumulative than quintozene, and may contribute to dietary residues, but this issue is not relevant to most uses of quintozene in New Zealand. The question of food residues from uses of quintozene is a matter for the New Zealand Food Safety Authority to consider.

No JMPS specification for quintozene has been established. In the Netherlands (when the product was in use which is over a decade ago), the maximum specified concentration of QCB was 1.0% (IPCS, 1989). However, information available to ERMA New Zealand indicates that actual concentrations of these impurities in currently manufactured quintozene are much lower, The Canadian regulator (PMRA, 2009) reported that the maximum concentration in technical grade quintozene were less than 350 and 100 ppm respectively for HCB and QCB.

ERMA New Zealand proposes the following maximum impurity levels should apply to technical grade quintozene[23]:

Hexachlorobenzene (HCB)	0.05%
Pentachlorobenzene (QCB)	0.01%

[23] Based on confidential information from the registrant ERMA New Zealand understands the AMVAC product can comply with the proposed HCB specification, but at present has no information in respect to the QCB impurity levels. Since the product is primarily made for the North American market ERMA New Zealand assumes that it will comply with North American specification requirements.

F1.3.2 Carcinogenicity

Quintozene has been classified a group C carcinogen by the US EPA based on hepatocellular hypertrophy and hyperplasia, and thyroid hypertrophy. In the studies carried out for the National Toxicology Program, a compound-related increase in tumours was not seen in Osborne-Mendel rats and B6C3F1 mice. ERMA New Zealand has not proposed the classification of quintozene for carcinogenicity based on these data. Mechanistic information suggests quintozene is non-genotoxic. There is an indication of increased cell turn over in liver and thyroid and a disturbance of hypothalamic pituitary thyroid axis in rodents for which toxicological relevance to humans is at least questionable.

ERMA New Zealand considered whether a classification is appropriate relating to the impurities present, specifically HCB and QCB, and concluded that no classification on the basis of the impurities should be assigned, due to the low concentration of the impurities present (assuming the above specification is put in place). In respect to the dioxin contaminant the concentrations present are much lower, and while the impurities are very potent, the risk assessment in this reassessment is the more appropriate way in which to address the presence of the dioxin contaminant than a hazard classification.

ERMA New Zealand concluded that no classification for carcinogenicity should be applied.

F1.3.3 Reproductive and Developmental Toxicity

The JMPR (WHO, 2006) review includes summary information on reproductive and developmental toxicity. The reproductive toxicity data appear negative, with the possible exception of effects via lactation, but interpretation of the reports for the lactation effects are impacted by findings indicative of viral infections in the animals. Furthermore, the effect may be the result of contaminants present (HCB and QCB) at higher concentration than in the proposed quintozene specification.

In the developmental studies, the JMPR review indicated no developmental toxicity in rats in the more recent and reliable studies. The rabbit data are were more difficult to assess, and the conclusion of the ERMA New Zealand review was that the developmental effect if seen occurred a doses above the NOEL for maternally toxicity.

ERMA New Zealand concluded the data do not support classification for reproductive or developmental toxicity.

F1.3.4 Target organ toxicity

The primary data available for classification for repeat dose target organ toxicity are the chronic feeding studies for rats and mice, for which a NOAEL at 1 mg/kg bw/day was proposed by the EPA based on liver and thyroid lesions. ERMA New Zealand does not consider that the thyroid effects in the rodents are human toxicological relevance. The liver induction effects seen are considered human relevant and these findings are confirmed in other studies relating to target organ toxicity discussed below under derivation of the AOEL by increase liver weights. The data set confirms that the LOAEL values are in the range between 10 and 100 mg/kg bw/day for a 90 day study appropriate for classification of 6.9B (via the oral route) so no change to the current classification of quintozene is proposed.

JMPR reports a NOAEL of 300 mg/kg bw/day in a 21 day repeat dose dermal study in rats, with the LOAEL at that a dose of 1000 mg/kg bw/day. ERMA New Zealand concluded that these data support the conclusion that no classification for repeat dose target organ toxicity via that dermal route should apply since the LOAEL is outside the classification criteria in ERMA, 2008.

F1.4 Agency conclusion on revised classification of technical grade quintozene

As a result of the above review, ERMA New Zealand's classification of technical grade quintozene is unchanged. This conclusion is based on the assumption that the impurity specifications above for HCB and QCB are applied.

Table F.2: Class 6 classification of quintozene technical active ingredient

Endpoint	Current HSNO Classification*	Proposed HSNO Classification
Eye irritant	6.4A	6.4A
Contact sensitiser	6.5B	6.5B
Target organ toxicant	6.9B	6.9B

* There is no HSNO approval for quintozene as no separate transfer approval for quintozene was established in the HSNO Chemicals Transfer Notice 2006. The only HSNO approval is for the single formulated product containing quintozene.

Since no change the classification of quintozene is proposed, no changes to the classification of the approved substance (Table F.3) are proposed as a result of this reassessment.

Table F.3: HSNO Class 6* classifications of "Water dispersible granule or wettable powder containing 750 g/kg quintozene", Approval No HSR00742

Transfer classification
Eye irritant (6.4A), Contact sensitiser (6.5B), Target organ toxicant (6.9B)

* The ecotoxicity classifications are addressed in Appendix D.

The classification of formulation is a HSNO approval established in the HSNO (Pesticides) Transfer Notice 2004 (as amended). http://www.ermanz.govt.nz/resources/publications/pdfs/gn72.pdf

F1.5 Acceptable Operator Exposure Limit (AOEL) for quintozene

No AOEL has been set by the EU for quintozene. There is no AOEL listed in Footprint. http://sitem.herts.ac.uk/aeru/iupac/581.htm Quintozene is a banned pesticide active ingredient in Europe.

ERMA New Zealand therefore used reviewed the data from the EPA RED document and JMPR review to provide the basis for derivation of the AOEL.

The US EPA derived a chronic reference dose (CRfD) of 0.01 mg/kg bw/day, based on the NOAEL of 1.0 mg/kg/day from a chronic toxicity study in rats. The LOAEL was 150 mg/kg bw/day. The adverse effects observed at the LOAEL were hepatocellular hypertrophy and hyperplasia, and thyroid hypertrophy. Intra- and interspecies uncertainty factors were 10 and 10, giving an overall uncertainty factor of 100. As

discussed above under carcinogenicity and target organ toxicity the thyroid effects are not considered of relevance to human exposures, but the liver induction is likely of relevance.

End points of relevance from the JMPR review (WHO, 2005) are:

- A NOAEL of 3.07 mg/kg bw/day was identified in a 13 week study in Charles River rats, based on minimal changes in body weight gain, increased liver weight and changes in alanine aminotransferase activity at high doses (~187 and 381 mg/kg bw/day for males). [ERMA New Zealand notes the study only used 15 animals per sex per group.] (McGee, 1988 cited by WHO,2005)
- A NOAEL of 1 mg/kg bw/day (40 ppm) in 4 week study dogs was identified as "probable" based on changes in liver weight and clinical chemical parameters at higher doses 2000 and 4000 ppm (~50 and 100 mg/kg bw/day), but the JMPR report documents inadequacies in the information available (Johnson 1989, cited by WHO 2005.)
- A NOAEL of 1 mg/kg bw/day (20 ppm in diet) in a multigeneration reproductive toxicity study in rats, on the basis of changes in body weight in pups and adults at the 3000 ppm (~150 mg/kg bw/day). (Schardein, 1991 cited by WHO, 2005)

ERMA New Zealand notes that overall, the database supports the use of a NOAEL of 1 mg/kg bw/day since the JMPR intermediate dose studies support this value and the longer term studies and the chronic NOAEL used by the EPA to derive the CRfD are also relevant in respect to liver effects.

In the absence of any information on the proportion of the absorbed dose absorbed, ERMA New Zealand assumed 100% absorption, a factor of 1.0. The JMPR review (WHO, 2005) suggests considerable variability in the proportion of dose absorbed depending on the species, age, and sex. ERMA New Zealand considers however, that the JMPR data are not of such clarity that it is possible to be definitive on what value should be used for rodent NOEL from which the AOEL is being derived. No fully detailed toxicokinetic studies are presented. ERMA New Zealand further notes that while the proportion of quintozene remaining in faeces at the end of studies in Rhesus monkey is approximately up to 20% of the dose (12.9 – 16.3%), it cannot be safely concluded that this quintozene had been absorbed. It could have been absorbed and excreted unchanged. Furthermore, even if up to 16% had not been absorbed, this would suggest 84% absorption, which is relatively high proportion. The key issue is what value should be applied in relation to the rodents, but the biotransformation studies reported on rodents by JMPR are relatively old (mostly pre 1980), and ERMA New Zealand does not consider them reliable. In one study, rabbits given very high doses of 1, 2 and 3 g by gavage suffered anorexia. The study claims that analysis demonstrated absorption of (only) 54, 38 and 41% of the administered dose, but the study is old (1955), and the JMPR review does not indicate how these proportions were established.

In conclusion, ERMA New Zealand has assumed 100% absorption, noting however, that this gives a higher AOEL than would lower assumption, so this assumption is not conservative.

The calculation of the AOEL is as follows:

$$\text{AOEL} = \frac{\text{NOEL (most relevant study) x absorption factor}}{\text{Safety Factors}}$$

$$\textbf{AOEL} = \frac{\text{1.0 mg/kg bw/day x 1.0}}{100} = \textbf{0.01 mg/kg bw/day}.$$

AOEL for quintozene = 0.01 mg/kg bw/day

The AOEL for quintozene was used for the assessment of bystander exposures to quintozene, although ERMA New Zealand has recently (since early 2010) used the chronic reference dose for this purpose. The AOEL was used largely due to the limited review of quintozene dataset.

F1.6 Dermal absorption

The EPA RED (US EPA, 2006 refers in footnote 5 (p83) to use of a dermal absorption value of 33%. No indication is given on whether this was used for both the formulated product and diluted spray so this was assumed to be the case.

In the proposed reassessment document from the PMRA from 2009 [which is not a final document, but is available on the PMRA web site (PMRA, 2009)] there is reference to use of "33% of the oral". What this means is not entirely clear. In the same table (p26 of the document) there is a reference for the inhalation criteria to inhalation using "100% of the oral". This information has been interpreted by ERMA New Zealand as meaning what proportion is absorbed in the normal manner during modelling. This is supported by the observation that use of 100% absorption for inhalation is universal, and that the US EPA RED, on which the PMRA review was based, refers to 33% as the proportion absorbed.

F2 A brief summary of the toxicological effects of dioxin and adoption of the tolerable monthly intake (TMI)

F2.1 Introduction

This reassessment has been undertaken due to the presence of the dioxin contamination in the approved quintozene formulation which was not known to the Authority at the time of the transfer approval. A major focus of the reassessment is therefore the toxicological significance of the dioxin content. The purpose of this appendix is to briefly summarise the toxic effects of dioxin and to establish the basis for the tolerable monthly intake (TMI) value used for human risk assessment in New Zealand. The TMI has been adopted from work by the Ministry of Health and the Ministry for the Environment.

F2.2 Dioxin and dibenzofuran congeners and toxic equivalence

Dioxin is the term used in this document to represent the combination of toxicologically significant polychlorinated dibenzo-para-dioxins and polychlorinated dibenzofurans dioxin and dibenzofuran congeners. Throughout this document "dioxin" is used to refer to the dioxin concentration expressed as the toxic equivalent concentration (dioxin

TEQ), rather than a specific congener. The dioxin TEQ is essentially the concentration of 2,3,7,8- tetrachlorodibenzo-para-dioxin (TCDD) which would exert the equivalent toxicological effect to the mixture.

Appendix A3 lists the different dioxin congeners of toxicological significance and their associated toxic equivalency factors (TEF). Comparison of the potency of the other congeners is then reflected in the application of an appropriate toxic equivalent factor (TEF). This results in an ability to assess the toxicological significance of complex mixtures and is an internationally agreed approach.

The different congeners of dioxin have not been evaluated separately, so the toxicological effects discussed here are those found for TCDD, which is the congener which has been most extensively studied in animal models and which some human populations have been exposed to due to accidents during industrial manufacturing of chlorophenols.

F2.3 Toxicology of dioxin

The main toxicological effects for dioxin (JEFCA, 2002) are:

- Acute toxicity is high and is characterized by a generalized wasting syndrome. The response is very variable in different species. (These acute effects are not relevant to the exposures that are likely to occur from use of quintozene.)
- Chloracne (from high acute doses). This appears to be a toxic effect specific to human (rather than other mammalian species including primates) and is also the most reliably and consistently seen effect in humans from acute dioxin exposures. Nevertheless, the response is variable within the human population based on serum dioxin concentration (body burdens). (Chloracne is not relevant to the dioxin exposures that would be likely to occur from use of quintozene.)
- Developmental toxicity in offspring identified in early adulthood.
- Cancer. IARC has placed dioxin in group 1A as a proven human carcinogen based on an increase in cancer at all sites. This is a conclusion that has never been established for any other carcinogen. Dioxin exposure causes tumours in laboratory animals at multiple sites particularly in the liver. A non genotoxic mechanism is believed to be responsible for carcinogenicity resulting from dioxin exposure.
- Target organ toxicity: Extremely potent inducer of particular enzyme systems. Immune system suppression has been identified in mice after *in utero* exposure. Endometriosis was identified in one study in female Rhesus monkeys after prolonged exposure.

Dioxin itself has not been assigned a HSNO classification, but it is clear from the above summary that for the class 6 repeat dose toxicity endpoints, a classification of dioxin would include those set out in Table F.4.

Table F.4: Dioxin HNSO Class 6 Classification (Information only: Not formally proposed)

Class 6 endpoint	Toxic effect
6.7A	IARC Group 1 proven human carcinogen
6.8A	Produces reproductive and developmental effects in animals and humans
6.9A	Potent target organ toxicant for multiple organs and cell types, a very potent activator of metabolic enzymes

The reason why no such classification has been applied is that dioxin is a contaminant at low concentration and it should be managed by means of an exposure and risk assessment rather than a hazard assignment.

F2.4 Adoption of the Tolerable Monthly Intake (TMI) for the Dioxin

In 1998 WHO held an expert meeting with the aim of establishing a tolerable daily intake (TDI) for dioxin. The report of the meeting was published by in van Leeuwen et al., 2000.

The key studies from which the WHO TDI range was derived are set out in table below.

Table F.5: Key studies used in the derivation of human health criteria.

Species	Biological effect	References[24]
Sprague-Dawley rats	Cancer. The carcinogenicity findings were hepatocellular carcinoma, squamous-cell carcinoma in lung and hard palate	Kociba et al., 1978
Long Evans Hooded rats	**Decreased sperm count in offspring; increased genital malformations in offspring (delayed vaginal opening)**	**Gray et al., 1997a, Gray et al., 1997b**
Rats	**Immune suppression in offspring**	**Gehrs et al., 1997; Gehrs and Smialowicz, 1998**
Rhesus monkeys	**Neurobehavioural effects in offspring**	**Schantz and Bowman,1989; Schantz et al., 1992**
Rhesus monkeys	Endometriosis	Rier et al., 1993

The effects seen in these studies may be summarized as follows:

The WHO consultancy focused on the reproductive and developmental endpoints which occurred at the lowest body burdens in the species studied. It was the developmental toxicity which occurred at lower body burdens in the rats and monkeys in the range of 10–50 ng/kg bw.

The equivalent daily intake that would generate the equivalent body burden in the human population was calculated based on the estimated half-life of dioxin in humans of 7 years, which gave a range of 10-40 pg/kg bw/day. Due to the toxicokinetics being address in deriving this human equivalent dose an uncertainty factor of 10 was applied

[24] References as cited by van Leeuwen et al., 2000

to these data to give the recommended TDI range of 1 – 4 pg/kg bw/day. It was recommended by the WHO committee that driving intakes to the lower end of this range should be the objective.

A more detailed review of the toxic effects of dioxin has not been included in this application as other authoritative reports reviewing the data which lead to the WHO TDI are readily available. For example from the Ministry for the Environment's website at from this page:
http://www.mfe.govt.nz/publications/hazardous/dioxin-evaluation-feb01.html

As a result of the recognition of the importance of the longer term average intakes (and body burdens), the TDI has subsequently been interpreted as a monthly intake. Thus an Interim Maximum Monthly Intake (IMMI) of 30 pg TEQ/kg bw/month was set following a recommendation from expert review group, the Organochlorines Technical Advisory Committee (OTAG) in 2002.
http://www.moh.govt.nz/moh.nsf/Files/PHP/$file/publichealthperspectives-5-4.pdf

The Ministry of Health, 2010 confirmed (personal communication J Waters/N Foronda, 16 November, 2010) that the above IMMI is the current monthly dioxin intake standard.

F2.5 Other Monthly Intake Values

The Australian OCSEH has used a TMI of 70 pg TEQ/kg bw/day (OCS, 2004), based on the Permissible Tolerable Monthly intake (PTMI) set by JECFA, 2002. Two studies were considered critical for the derivation of this PTMI.

(i) Ohsako, et al. 2001 (cited by OCS, 2004)

Exposure of Holtzman rats on day 15 of gestation to a bolus dose of 0 – 800 mg 2,3,7,8-TCDD/kg bw resulted in reduced weight of the ventral prostate and reduced ano-genital distance.

(i) Faqi, et al, 1998 (cited by OCS, 2004)

Exposure of Wistar rats loading and maintenance dose (s.c). on day 15 of gestation to a bolus dose of 0 – 800 mg 2,3,7,8- TCDD/kg bw resulted in decrease sperm production and altered sexual behavior in male offspring.

The Joint Expert Committee of FAO/WHO on Food Additives (JECFA) established a provisional tolerable monthly intake (PTMI) of 70 pg TEQ per kg body weight per month (approximately equivalent to 2.3 pg TEQ per kg body weight per day) (JEFRA, 2002) The summary wording is:

> "The range of PTMIs derived from the two studies, with either the linear or the power model to extrapolate the maternal body burden with single to multiple doses, is 40–100 pg/kg bw per month. The Committee chose the mid-point of this range, 70 pg/kg bw per month, as the PTMI."

The TMI was derived as the mid-point of the range between two studies, Ohsako et al, 2001 and Faqi et al, 1998, for which the safety factors were 3.2 and 9.6 applied respectively to the equivalent human monthly intake (EHMI).

For the Ohsako study the factor of 3.2 represent a factor to represent different toxicodynamics among the human population (the EHMI negating the need for consideration of toxicokinetic difference between human and the animal model). For the Faqi study the factor of 3.2 represent a factor to represent different toxicodynamics among the human population (the EHMI negating the need for consideration of toxicokinetic difference between human and the animal model) but an additional factor of 3 was applied to take account of the use of a LOEL in place of a NOEL.

F2.6 Conclusion on the TMI

The core data for derivation of the TMI for dioxin is that of the WHO leading to the tolerable daily intake (TDI) of 1 – 4 pg/kg bw/day. Newer data were used in the JECFA review, but the findings are essentially similar. Various international and national regulators have interpreted the WHO TDI range differently, but soon after its derivation the New Zealand Ministry of Health adopted the low end of the this TDI range for exposure and risk assessment.

Reflecting the fact that it is longer term average intakes of dioxin which are of significant, the Ministry of Health used the low end of the range to derive a monthly intake value, the interim maximum monthly intakes (IMMI), and this value is still current. Therefore, ERMA New Zealand has used this value as the Tolerable Monthly Intake (TMI) in this exposure and risk assessment.

Tolerable monthly intake (TMI) for dioxin = 30 pg dioxin TEQ/kg bw/day

Appendix G: Human Exposure and Risk Assessment for Quintozene

G1 Introduction

Table G.1 sets out the use patterns for use of Terraclor 75WP in New Zealand.

Table G.1: Use patterns for Terraclor 75 WP

Use	Method of application	Application rate (product)	Application rate (quintozene)	Frequency
Turf (recreational)	Assumed to be low boom	30 g/10 m^2 in 5 litres of water, equivalent to 30kg/ha.	22.5 kg a.i./ha[$] in 5000 litres of water.	Monthly
Seedling post planting	Back pack, low target	50g in 100 L water, apply 100 -200ml per plant	Rate /hectare calculated to be 1.275 kg a.i./ha[$] (based on tomato density of 17,000 plant/ha).	Once per crop, 4 crops/year/ site. Assuming use on 1 or 20 days/month
Pre-sowing soil	Back pack low target or low boom	1.2 kg/100 m^2, equivalent to 120 kg/ha. Worked into the soil to 15 cm, post application.	90 kg a.i./ha[$] Worked into the soil to 15 cm, post application*.	Once per crop, 4 crops/year/ site. Assuming use on 1 or 20 days/ month
Empty seed boxes	Back pack, low target	12g in 3L per 1 m^2	90 kg a.i./ha[$]	Assumed as for pre-sowing
Bulbs	Manual dipping, drenching and planting in treated soil.	No information provided	Modelling of mixing/loading exposures carried out based on use of upper end of 20 – 40L of mixture containing 1% of the product. [$]	Assuming use on 1 or 20 days/ month

[$] The use patterns give rise to four main application rates which are modelled: one for turf and two for seedlings (pre or post planting), and one for bulb uses. The use on empty seed boxes was not modeled.

ERMA New Zealand has modelled the human exposure and risk from use of Terraclor 75WP both with respect to the quintozene active ingredient and the dioxin contaminant present in the product. Primarily operator and re-entry exposures were estimated using the UK CRD interpretation of the German BBA operator exposure model (CRD, 2010a). Bystander exposures were estimated using a combination of CRD approaches for estimating toddler exposures and the US EPA approach which incorporates soil ingestion by the toddler. Where necessary (e.g. for bulb treatments), ERMA New Zealand has adapted the model approaches in order to approximate exposures where no directly appropriate models are available.

G2 Operator Exposure Modelling for Quintozene

In Table G.2 ERMA New Zealand listed the input parameters used for the exposure modelling for quintozene.

Table G.2: Input parameters for quintozene exposure assessment

Parameter	Value
Concentration of quintozene in product	750 g quintozene/kg
Formulation type	wettable powder
Application rate	Turf: 22.5 kg quintozene/ha Seedlings: 90 kg quintozene/ha Seedlings: 1.275 kg quintozene/ha (tomatoes) Bulbs: Dip treatment in 1% solution.
Application methods	• Boom spray (low boom) • Backpack sprayer (low target) [Backpack sprayer (high target) used as no model estimates for a low target are available.] • Dipping: Modelling of mixing/loading exposures only.
Frequency of use and treatment interval	Turf: 4 applications per year at monthly intervals Seedlings: Single application per planting, pre-planting or immediately post planting [ERMA New Zealand has assumed multiple applications at a particular site for different seed batches]
Dermal Absorption (quintozene)	33% (from Appendix F)
AOEL (quintozene)	0.01 mg/kg bw/day (from Appendix F)

G2.1 Results from use on turf

In Table G.3 the operator exposures from turf uses with the use of various levels of personal protective equipment are set out.

Table G.3: Operator exposure and risk estimates for quintozene from turf uses at 22.5 kg quintozene/ha

Estimated exposure to quintozene for 70 kg operator under five different exposure scenarios as predicted from the UK PSDs interpretation of the BBA Model and associated RQ estimates from use of Terraclor 75 WP for turf		
Boom		
Exposure scenario	**Estimated operator exposure (mg/kg bw/day)**	**Risk Quotient**
No PPE during mixing, loading and application	17.51	1751
Gloves only during mixing and loading	4.91	491
Gloves only during application	16.71	1671
Full PPE during mixing, loading and application (excluding respirator)	0.77	77
Full PPE during mixing, loading and application (including respirator)	0.32	32

Backpack – high level target		
Exposure scenario	**Estimated operator exposure (mg/kg bw/day)**	**Risk Quotient**
No PPE during mixing, loading and application	9.94	994
Gloves only during mixing and loading	4.69	469
Gloves only during application	8.83	883
Full PPE during mixing, loading and application (excluding respirator)	0.58	58
Full PPE during mixing, loading and application (including respirator)	0.22	22

The operator exposure estimates for both application methods for quintozene application to turf are unacceptable with any of the available levels of personal protective equipment (PPE).

No model for low level target is available for backpack sprayer, which ERMA New Zealand notes would be more appropriate. The exposure estimates for backpack sprayer for a high level target are likely to be precautionary. Nevertheless, the risk estimates are so high that it is unlikely that modelling for a low target would reduce the estimates to an acceptable level, particularly as the majority of the exposure occurs during the mixing and loading stage which will be the same regardless of the target plant height.

G2.2 Results from use on seed bed uses

ERMA New Zealand modelled two application rates for seed bed uses, one to reflect the top application rate and a lower rate based on drenching of individual tomato plants in the field based on estimated plant density. The model used was for a back pack sprayer with a high target although in this circumstance a low target is more likely, as the only exposure models available from the BBA are for high targets.

In Table G.4 the operator exposures to quintozene from seed bed uses with the use of various levels of personal protective equipment are set out using the highest estimated application rate of 90 kg quintozene/ hectare.

Table G.4: Operator exposure and risk estimates for quintozene from seed bed uses at 90 kg quintozene/ha

Estimated exposure to quintozene for 70 kg operator under five different exposure scenarios as predicted from the UK PSDs interpretation of the BBA Model and associated RQ estimates from the use of Terraclor 75WP for seed beds		
Boom		
Exposure scenario	**Estimated operator exposure (mg/kg bw/day)**	**Risk Quotient**
No PPE during mixing, loading and application	70.05	7005
Gloves only during mixing and loading	19.65	1965
Gloves only during application	66.86	6686
Full PPE during mixing, loading and application (excluding respirator)	3.07	307
Full PPE during mixing, loading and application (including respirator)	1.28	128

Backpack - high level target		
Exposure scenario	**Estimated operator exposure (mg/kg bw/day)**	**Risk Quotient**
No PPE during mixing, loading and application	39.77	3977
Gloves only during mixing and loading	18.77	1877
Gloves only during application	35.32	3532
Full PPE during mixing, loading and application (excluding respirator)	2.30	230
Full PPE during mixing, loading and application (including respirator)	0.90	90

In Table G.5 the operator exposures to quintozene from seed bed uses with the lowest estimated application rate of quintozene for tomato seedlings are estimated. The application rate of 1.275 kg quintozene/ha is based on the application to each plant of up to 200 ml of a solution produced by diluting 50 g Terraclor 75WP in 100 L water. The quantity of quintozene applied per plant is 0.075 g quintozene/plant [50/100 x 0.2 x 75/100]. The tomato plant density has been assumed to be 17,000 plants/ha, so the application rate per hectare is 1,275 g/ha, which is 1.275 kg quintozene/ha.

Table G.5: Operator exposure and risk estimates for quintozene from seed bed uses at 1.275 kg quintozene/ha (field tomatoes)

Exposure scenario	Estimated operator exposure (mg/kg bw/day)	Risk Quotient
No PPE during mixing, loading and application	0.9924	99.24
Gloves only during mixing and loading	0.2783	27.83
Gloves only during application	0.9472	94.72
Full PPE during mixing, loading and application (excluding respirator)	0.0435	4.35
Full PPE during mixing, loading and application (including respirator)	0.0181	1.81

These operator exposure estimates for quintozene from application to seed bed uses by all application method that can be modeled are unacceptably high even with full personal protective equipment (PPE), including a respirator.

No model for low level target is available for backpack sprayer, which ERMA New Zealand notes that would be more appropriate. The exposure estimates for backpack sprayer for a high target are likely to be precautionary. Nevertheless, the risk estimates are so high that it is unlikely that modelling for a low target would reduce the estimates to an acceptable level particular as the majority of the exposure occurs during the mixing and loading stage which will be the same regardless of the target plant height.

G2.3 Results from use on bulb uses

ERMA New Zealand is unaware of any exposure models which could be used to assess exposure to operators from bulb dipping. As a consequence ERMA New Zealand has only assessed exposure to operators from the mixing and loading of the product into a container and not considered exposures from either the actual bulb dipping or handling either the bulbs or the trays/containers after dipping. This will significantly underestimate the actual risk to operators involved in bulb dipping.

ERMA New Zealand calculated the mixing loading exposures based on advice from growers that batches of up to 40 litres batch of solution are made up for use on a single day. The information received is that the batch consists of 1 % of product (so 0.4 kg of product or 0.3 kg of quintozene is needed for the 40L batch). ERMA New Zealand has then used the assumptions from the UK interpretation of German BBA model regarding the operator exposure during mixing and loading to estimate exposure.

HExp = Hand exposure to wettable powers during mixing and loading = 6 mg of a.i/kg a.i handled per day.

IExp = Inhalation exposure to wettable powers during mixing and loading =0.07 mg a.i./kg a.i. handled per day.

For quintozene hand exposure the exposure is given by:

Exposure = Hexp x M x D

= 6 x 0.3 x 0.33= 0.594 mg

Where:

HExp = 6 mg a.i/kg a.i. handled per day
M = quantity of a.i handled/day, 0.3 kg/day.
D = dermal absorption (proportion as fraction), 0.33

For quintozene inhalation exposure the exposure is given by:

Exposure = Iexp x M x R

= 0.07 x 0.3 x 1.0 = 0.021 mg

Where:

IExp = 6 mg a.i/kg a.i. handled per day
M = quantity of a.i handled/day, 0.3 kg/day.
R = respiratory absorption (proportion as fraction), 1.0

Total exposure therefore = 0.594 + 0.021 = 0.615 mg/day

Assuming an operator weights 70 kg daily exposure on a body weight basis = 0.615/70 = 0.00878 mg/ kg bw/day

Therefore the Risk Quotient (RQ) = 0.00878/0.01 **= 0.88**

ERMA New Zealand estimated the impact of the use of PPE on this exposure. If gloves are worn and these gloves are assumed to reduce hand exposure by 90 % (a default assumed in the BBA model), the exposure can be reduced, as the hand exposure become 10% of previous estimate.

Therefore the total exposure with PPE becomes = 0.0594 +0.021 = 0.0804 mg/day. Assuming an operator weights 70 kg daily exposure = 0.0804/70 = 0.00115 mg/ kg bw/day. Therefore the Risk Quotient (RQ) = 0.00115/0.01 = **0.11**

It should be pointed out that this assumes that gloves always deliver a high level of protection (90%). In some instances this assumption will be unrealistic as the protection provided by the gloves will depend on the material and physical condition of the gloves (break through time) as well as operator behavior (the procedure used for removal of contaminated gloves and washing of gloves after each use).

G3 Re-entry exposures to quintozene

G3.1 Re-entry exposures from turf use

ERMA New Zealand notes that there are several transfer coefficients available from other regulators for re-entry activities on turf. These range from 500 cm^2/hr (which represents activities with low contact with the turf, for example mowing turf) to 16500 cm^2/hr (which represents activities with high contact with the turf, for example, manual weeding turf) (USEPA, 2010a). In this exposure assessment ERMA New Zealand has used the low contact value because ERMA New Zealand considers that regular manual weeding activity on specialised turf is relatively unlikely. In respect to turf farm operations ERMA New Zealand has no information on work practices, in particular timing of quintozene application in relation to harvest or laying of turf so no assessment of such activities was possible.

Re-entry worker exposures are calculated by estimating the exposure of workers entering a crop that has been sprayed and comparing this to the AOEL. Worker exposure is based on dermal exposure only, inhalation exposure is assumed to be insignificant. Exposure occurs by contact with foliar residues. Re-entry exposure was estimated using a modified version of the approach used by the UK Chemical Regulation Directorate (CRD, 2010b). ERMA New Zealand used a maximum of 2 applications at a 30 day interval for its assessment.

E = DA*DFR *AR*TC*WR/BW

Where E= Exposure
DA = percentage dermal absorption (33 %)
DFR = Dislodgeable foliar Residue per kg a.i/ha (as no values were available use assume 3.0 ug a.i./cm^2 per kg a.i. As there are multiple applications the DFR following the final application was estimated using the FOCUS formula (FOCUS, 2010). The DFR immediately following the n^{th} application ($DFR_{n(a)}$) is given by:

$$DFR_{n(a)} = DFR_{single\text{-}application} \times (1-e^{-nki})/(1-e^{-ki})$$

Where n is the number of applications =2
k is the rate constant for foliar dissipation (0.019 assuming that quintozene has a foliar half life of 35 days (USEPA, 2010b)
i is the interval between applications = 30 days.

AR = Application rate 22500 g/ha
TC = Transfer coefficient: 500 cm^2/hr
WR = 8 hrs
BW = Body weight (assume an operator is 70 kg)

The exposure 24 hours after application has been completed was calculated to reflect the possible decay of residue which gives 3.006 mg/kg bw/day, therefore the Risk Quotient (RQ) value = 3.006/0.01 = 300.

Assuming that the foliar half life is 35 days, ERMA New Zealand calculated that it would take 289 days before the exposure to an operator would become acceptable (RQ < 1). Given the high RQ values and very long re-entry interval with the lowest transfer

coefficients and the lowest application rates, ERMA New Zealand has not conducted further assessment of worker re-entry exposure, since the risks and re-entry intervals of the other scenarios would all be by definition unacceptable.

G3.2 Re-entry exposures from seed bed uses (field tomatoes)

Re-entry worker exposure are calculated by estimating the exposure of workers entering a crop that has been sprayed and comparing this to the AOEL. Worker exposure is based on dermal exposure only, inhalation exposure is assumed to be insignificant. Exposure occurs by contact with foliar residues. Re-entry exposure was estimated using a modified version of the approach used by the UK Chemical Regulation Directorate (CRD, 2010b).

E = DA*DFR *AR*TC*WR/BW

Where E= Exposure
DA = percentage dermal absorption (33 %)
DFR = Dislodgeable foliar Residue per kg a.i/ha (as no values were available use assume 3.0 ug a.i./cm^2 per kg a.i.
AR = Application rate 1275 g/ha
TC = Transfer coefficient: 4500 cm^2/hr
WR = 8 hrs
BW = Body weight (assume an operator is 70 kg)
Foliar half life of quintozene = 35 days

Using this foliar half live value, the predicted exposure 24 hours after application was calculated as 0.64 mg/kg bw/day therefore the Risk Quotient (RQ) value = 0.64/0.01 = 64

ERMA New Zealand notes that the use of 35 days, the default value, for a relatively persistent material such as quintozene is not precautionary.

G4 Bystander exposures to quintozene

Bystander exposure was estimated by estimating the exposure of a toddler 8 m away from the edge of the application area to turf and soil exposed to spraydrift. Exposure was assumed to come from dermal exposure, hand to mouth, object to mouth and the incidental ingestion of soil (USEPA, 2007) (CRD, 2010a). Estimates of spraydrift were assumed to be the same as the low boom fine droplets scenario from the AGDRIFT model (APVMA, 2010). The model also estimates what buffer zone would be required to bring the exposure for the toddler down to an acceptable level.

G4.1 Bystander exposures and risks from turf uses

ERMA New Zealand estimated the exposure for the toddler on the basis of two applications at an interval of 30 days. ERMA New Zealand recognised that 4 applications/year are allowed for in Table 5, but ERMA New Zealand's standard approach is to model for two repetitions at the appropriate interval as this appears to be a common approach by regulators working in this area. This uses the foliar DT_{50} of 35 days from the US EPA RED document, but this is the default value and is not based on specific data for quintozene. The exposure and risk estimates for a toddler as a representative bystander are set out in Table G.6.

Table G.6: Estimated exposure to quintozene of 15 kg toddler exposed through contact to surfaces 8 m from an application area for turf

Exposure scenario	Estimated exposure of 15 kg toddler exposed through contact to surfaces 8 m from an application area (ug/kg bw/day)	Risk Quotient	Buffer zone needed to reduce toddler exposure to RfD
Turf (2 applications at 30 day intervals) 90000 kg a.i./ha	150.50	15.0496	148
Seed beds 1 application 22500 kg a.i./ha	388	38.8	>304
Seed bed tomatoes 1275 g a.i./ha (1 application)	5.49	0.5494	6

* The Folar DT50 (half life for decay) of quintozene is assumed to be 35 days.

For application to turf and seed beds (at the highest rate) using a **low boom, fine droplet spray** which is most likely for the fungicide, the risk estimates for the toddler are high, even at a distance of 8 m away. Since the buffer zones that would be required to protect a toddler for both treatment scenarios are greater than 100m, this raises serious concerns. ERMA New Zealand expects that quintozene would often be used adjacent to residential properties.

G5 Conclusions of Human Health Exposure and Risk Assessment for quintozene

The outcome of the exposure and risk assessment conclusions for the use of Terraclor 75WP with respect to quintozene are:

G5.1 Quintozene

Operators

All the exposure estimates for operators to the active ingredient quintozene from the application of the substance for turf and seed bed uses were unacceptably high

The estimated exposures from bulb dipping as modeled tentatively as acceptable, but only an estimate of the exposure from mixing and loading was possible, the actual exposure is likely to be higher than estimated.

Re-entry workers

The estimated exposure of re-entry workers from use of quintozene on turf and seed bed were estimated as being unacceptable high based on the predicted quintozene exposure. The unprotected worker re-entry interval required for the estimated exposures are long.

Bystanders

The predicted bystander exposures to quintozene, calculated for a toddler as representative bystander, were estimated as unacceptably high for all the modeled application methods, for turf and seed beds. The predicted buffer zones that would be needed to reduce the exposure to an acceptable level were greater than 100 m, which the exception of a single treatment of field tomatoes for which the application rate is the lowest, in which case the buffer zone of 6 m would be sufficient.

Appendix H: Qualitative Descriptors for Risk/Benefit Assessment

Qualitative descriptors for risk/benefit assessment

This section describes how ERMA New Zealand staff and the Authority address the qualitative assessment of risks, costs and benefits. Risks and benefits are assessed by estimating the magnitude and nature of the possible effects and the likelihood of their occurrence. For each effect, the combination of these two components determines the level of the risk associated with that effect, which is a two dimensional concept. Because of lack of data, risks are often presented as singular results. In reality, they are better represented by 'families' of data which link probability with different levels of outcome (magnitude).

The magnitude of effect is described in terms of the element that might be affected. The qualitative descriptors for magnitude of effect are surrogate measures that should be used to gauge the end effect or the 'what if' element. Tables H.1 and H.2 contain generic descriptors for magnitude of adverse and beneficial or positive effect. These descriptors are examples only, and their generic nature means that it may be difficult to use them in some particular circumstances. They are included here to illustrate how qualitative tables may be used to represent levels of adverse and beneficial (positive) effect.

Table H.1: Magnitude of adverse effect (risks and costs)

Descriptor	Examples of descriptions – ADVERSE
Minimal	Mild reversible short term adverse health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Local/regional short-term adverse economic effects on small organisations (businesses, individuals), temporary job losses No social disruption
Minor	Mild reversible short term adverse health effects to identified and isolated groups Localised and contained reversible environmental impact, some local plant or animal communities temporarily damaged, no discernible ecosystem impact or species damage Regional adverse economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job losses Potential social disruption (community placed on alert)
Moderate	Minor irreversible health effects to individuals and/or reversible medium term adverse health effects to larger (but surrounding) community (requiring hospitalisation) Measurable long term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium term individual ecosystem damage, no species damage Medium term (one to five years) regional adverse economic effects with some national implications, medium term job losses Some social disruption (e.g. people delayed)

Descriptor	Examples of descriptions – ADVERSE
Major	Significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community Long term/irreversible damage to localised ecosystem but no species loss Measurable adverse effect on GDP, some long term (more than five years) job losses Social disruption to surrounding community, including some evacuations
Massive	Significant irreversible adverse health effects reaching beyond the immediate community and/or deaths Extensive irreversible ecosystem damage, including species loss Significant on-going adverse effect on GDP, long term job losses on a national basis Major social disruption with entire surrounding area evacuated and impacts on wider community

Table H.2: Magnitude of beneficial effect (benefits)

Descriptor	Examples of descriptions – BENEFICIAL
Minimal	Mild short term positive health effects to individuals in highly localised area Highly localised and contained environmental impact, affecting a few (less than ten) individuals members of communities of flora or fauna, no discernible ecosystem impact Local/regional short-term beneficial economic effects on small organisations (businesses, individuals), temporary job creation No social effect
Minor	Mild short term beneficial health effects to identified and isolated groups Localised and contained beneficial environmental impact, no discernible ecosystem impact Regional beneficial economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job creation Minor localised community benefit
Moderate	Minor health benefits to individuals and/or medium term health impacts on larger (but surrounding) community and health status groups Measurable benefit to localised plant and animal communities expected to pertain to medium term. Medium term (one to five years) regional beneficial economic effects with some national implications, medium term job creation Local community and some individuals beyond immediate community receive social benefit.
Major	Significant beneficial health effects to localised community and specific groups in wider community Long term benefit to localised ecosystem(s) Measurable beneficial effect on GDP, some long term (more than five years) job creation Substantial social benefit to surrounding community, and individuals in wider community.

Descriptor	Examples of descriptions – BENEFICIAL
Massive	Significant long term beneficial health effects to the wider community
	Long term, wide spread benefits to species and/or ecosystems
	Significant on-going effect beneficial on GDP, long term job creation on a national basis
	Major social benefit affecting wider community

The likelihood applies to the composite likelihood of the end effect, and not either to the initiating event, or any one of the intermediary events. It includes:

- the concept of an initiating event (triggering the hazard), and
- the exposure pathway that links the source (hazard) and the area of impact (public health, environment, economy, or community).

Thus, the likelihood is not the likelihood of an organism escaping, or the frequency of accidents for trucks containing hazardous substances, but the likelihood of the specified adverse effect[25] resulting from that initiating event. It will be a combination of the likelihood of the initiating event and several intermediary likelihoods[26]. The best way to determine the likelihood is to specify and analyse the complete pathway from source to impact.

Likelihood may be expressed as a frequency or a probability. While frequency is often expressed as a number of events within a given time period, it may also be expressed as the number of events per head of (exposed) population. As a probability, the likelihood is dimensionless and refers to the number of events of interest divided by the total number of events (range 0-1).

Table H.3: Likelihood

Descriptor	Description
Highly improbable	Almost certainly not occurring but cannot be totally ruled out
Very unlikely	Considered only to occur in very unusual circumstances
Unlikely (occasional)	Could occur, but is not expected to occur under normal operating conditions.
Likely	A good chance that it may occur under normal operating conditions.
Highly likely	Almost certain, or expected to occur if all conditions met

Using the magnitude and likelihood tables a matrix representing a level of risk/benefit can be constructed.

In the example shown in Table H.4, four levels of risk/benefit are allocated: A (negligible), B (low), C (medium), and D (high). These terms have been used to avoid confusion with the descriptions used for likelihood and magnitude, and to emphasise

[25] The specified effect refers to scenarios established in order to establish the representative risk, and may be as specific as x people suffering adverse health effects, or y% of a bird population being adversely affected. The risks included in the analysis may be those related to a single scenario, or may be defined as a combination of several scenarios.

[26] Qualitative event tree analysis may be a useful way of ensuring that all aspects are included.

that the matrix is a tool to help decide which risks/benefits require further analysis to determine their significance in the decision making process.

For negative effects, the levels are used to show how risks can be reduced by the application of additional controls. Where the table is used for positive effects it may also be possible for controls to be applied to ensure that a particular level of benefit is achieved, but this is not a common approach. The purpose of developing the tables for both risk and benefit is so that the risks and benefits can be compared.

Table H.4: Level of risk

	Magnitude of effect				
Likelihood	**Minimal**	**Minor**	**Moderate**	**Major**	**Massive**
Highly improbable	A	A	A	B	B
Very unlikely	A	A	B	B	C
Unlikely	A	B	B	C	C
Likely	B	B	C	C	D
Highly likely	B	C	C	D	D

Appendix I: Examples of alternatives for quintozene use

Table I.1: Active ingredients used in alternative substances: Turf

Active ingredient	Hazard Classification														
	6.1 (O)[2]	6.1 (D)	6.1 (I)	6.4	6.5	6.6	6.7	6.8	6.9	9.1	9.2	9.3	9.4	Bioaccumulative	Rapid biodegradation
quintozene	**No**	**No**	**No**	**6.4A**	**6.5B**	**ND**	**ND**	**ND**	**6.9B**	**9.1A**	**ND**	**No**	**9.4A**	**Yes**	**No**
azoxystrobin	No	ND	C	No	No	No	ND	No	B	A	C	No	No	No	No
carbendazim*	E	ND	No	ND	ND	A	ND	A	B	A	B	No	No	No	No
chlorothalonil*	No	No	B	8.3A	B	No	B	No	A	A	B	B	No	No	No
fenarimol	E	ND	ND	A	No	No	ND	B	B	A	No	No	No	No	No
iprodione	E	ND	No	No	No	No	ND	No	B	A	No	No	No	No	No
mancozeb*	No	No	No	A	B	No	ND	ND	B	A	No	No	No	No	No
prochloraz	D	ND	ND	A	ND	No	ND	No	B	A	No	C	No	No	No
propiconazole[1]	D	ND	ND	A	No	No	No	No	B	A	No	C	No	No	No
tebuconazole	D	No	No	No	No	No	ND	ND	B	A	No	C	ND	No	No
thiophanate-methyl	E	No	D	No	B	B	ND	No	No	A	B	No	No	No	No
thiram*[1]	C	ND	C	A	B	ND	ND	ND	B	A	ND	B	No	No	Yes
trifloxystrobin	No	No	No	No	B	No	No	No	B	A	No	No	No	Yes	Yes

* chemical on the Chief Executive Initiated Reassessment (CEIR) list.
[1] these substances have also 6.3B classification
[2] O (oral), D (dermal), I (inhalation) routes

Table I.2: Active ingredients used in alternative substances: Ornamental and vegetable seedlings and bulbs

Active ingredient	Hazard Classification														
	6.1 (O) [2]	6.1 (D)	6.1 (I)	6.4	6.5	6.6	6.7	6.8	6.9	9.1	9.2	9.3	9.4	Bioaccum-ulative	Rapid biodegra-dation
quintozene	**No**	**No**	**No**	**6.4A**	**6.5B**	**ND**	**ND**	**ND**	**6.9B**	**9.1A**	**ND**	**no**	**9.4A**	**yes**	**no**
etridiazole	D	D	ND	A	No	ND	B	B	B	A	ND	C	ND	No	ND
boscalid	No	No	No	No	No	No	B	No	No	B	No	No	No	No	No
carbendazim*	E	ND	No	ND	ND	A	ND	A	B	A	B	No	No	No	No
chlorothalonil*	No	No	B	8.3A	B	No	B	No	A	A	B	B	No	No	No
copper hydroxide	D	No	ND	8.3A	B	ND	ND	ND	B	A	ND	B	ND	ND	No
fludioxonil	No	ND	ND	No	No	ND	ND	ND	B	A	No	No	No	Yes	ND
kresoxim-methyl	No	No	No	No	No	No	B	No	ND	A	No	No	C	No	No
metalaxyl-m*	D	No	No	A	B	No	No	No	B	C	No	B	No	No	No
propiconazole[1]	D	ND	ND	A	No	No	No	No	B	A	No	C	No	No	No
thiophanate-methyl	E	No	D	No	B	B	ND	No	No	A	B	No	No	No	No
thiram*[1]	C	ND	C	A	B	ND	ND	ND	B	A	ND	B	No	No	Yes
tolclofos-methyl	No	ND	D	No	ND	ND	ND	ND	B	A	ND	No	ND	Yes	No

* chemical on the Chief Executive Initiated Reassessment (CEIR) list.
[1] these substances have also 6.3B classification
[2] O (oral), D (dermal), I (inhalation) routes

Higher hazard classification compared to quintozene		**Same** hazard classification compared to quintozene		**Lower** hazard classification compared to quintozene	

Appendix J: Current Controls

HSNO Act controls

J.1 The controls applicable to the formulation containing quintozene are given in Table J.1. Control codes, as given in Table J.1, are codes ERMA New Zealand has assigned to enable easy cross-referencing to the regulations. These codes are detailed in ERMA New Zealand (2001).

J.2 Where a control has been changed from the default wording specified in the HSNO Regulations, this is indicated an asterix (*) next to the control code. The detail of this change, including deletion of a control, is listed in Table J.2.

Table J.1: Existing controls for 'Water dispersible granule or wettable powder containing 750 g/kg quintozene'

Substance / HSNO Control		Water dispersible granule or wettable powder containing 750 g/kg quintozene
Class 6, 8 and 9 controls	**T1**	✓*
	T2	✓
	T4	✓
	T5	✓
	T7	✓*
	E1	✓*
	E2	✓
	E3	✓
	E5	✓
	E6	✓
	E7	✓*
Packaging controls	**P1**	✓
	P3	✓
	P13	✓
	P15	✓
	PG3	✓
	PS4	✓
Disposal controls	**D4**	✓
	D5	✓
	D6	✓
	D7	✓
	D8	✓
Approved Handler	**AH1**	✓
Tracking	TR1	(*

Substance / HSNO Control		Water dispersible granule or wettable powder containing 750 g/kg quintozene
Emergency management controls	EM1	(
	EM6	(
	EM7	(
	EM8	(
	EM11	✓
	EM13	✓
Identification controls	**I1**	✓
	I3	✓
	I9	✓
	I11	✓
	I16	✓
	I17	✓
	I18	✓
	I19	✓
	I21	✓
	I23	✓
	I28	✓
	I29	✓

Table J.2: Summary of default controls applicable to quintozene containing substances

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001		
Code T1	Regs 11 – 27	Limiting exposure to toxic substances through the setting of TELs
Code T2	Regs 29, 30	Controlling exposure in places of work through the setting of WESs.
Code T4	Reg 7	Requirements for equipment used to handle substances
Code T5	Reg 8	Requirements for protective clothing and equipment
Code T7	Reg 10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles ***Changes to Default Controls*** This regulation applies to this substance, as if each item in Schedule 2 of the regulations relating to the specified hazard classification was replaced by: Hazard Classification / Liquid (L) / Solid (kg) 6.5B / 1 / 3
Code E1	Regs 32–45	Limiting exposure to ecotoxic substances through the setting of EELs ***Changes to Default Controls*** **Regulation 32 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001** Regulation 32 applies as if subclauses (1) and (2) were omitted.
Code E2	Regs 46 – 48	Restrictions on use of substances in application areas
Code E3	Reg 49	Controls relating to protection of terrestrial invertebrates e.g. beneficial insects
Code E5	Regs 5(2), 6	Requirements for keeping records of use
Code E6	Reg 7	Requirements for equipment used to handle substances
Code E7	Reg 9	Approved handler/security requirements for certain ecotoxic substances ***Changes to Default Controls*** **Regulation 9(1) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001** Regulation 9(1) is replaced by: This hazardous substance must be under the personal control of an approved handler when the substance is – a) Applied in a wide dispersive manner; or b) Used by a commercial contractor.

Hazardous Substances (Packaging) Regulations 2001		
Code P1	Regs 5, 6, 7(1), 8	General packaging requirements
Code P3	Reg 9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria
Code P13	Reg 19	Packaging requirements for toxic substances
Code P15	Reg 21	Packaging requirements for ecotoxic substances
Code PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III
Code PS4	Schedule 4	Packaging requirements as specified in Schedule 4

Hazardous Substances (Disposal) Regulations 2001		
Code D4	Reg 8	Disposal requirements for toxic and corrosive substances
Code D5	Reg 9	Disposal requirements for ecotoxic substances
Code D6	Reg 10	Disposal requirements for packages
Code D7	Regs 11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge
Code D8	Regs 13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge

Hazardous Substances (Personnel Qualifications) Regulations 2001		
Code AH1	Regs 4 – 6	Approved Handler requirements (including test certificate and qualification requirements)

Hazardous Substances (Tracking) Regulations 2001		
Code TR1	Regs 4(1), 5, 6	General tracking requirements ***Changes to Default Controls*** **Regulations 4 to 6 of the Hazardous Substances (Tracking) Regulations 2001** Regulations 4 to 6 are deleted.

Hazardous Substances (Emergency Management) Regulations 2001		
Code EM1	Regs 6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge
Code EM6	Reg 8(e)	Information requirements for toxic substances
Code EM7	Reg 8(f)	Information requirements for ecotoxic substances
Code EM8	Regs 12- 16, 18- 20	Level 2 information requirements for suppliers and persons in charge
Code EM11	Regs 25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans
Code EM13	Reg 42	Level 3 emergency management requirements: signage

Hazardous Substances (Identification) Regulations 2001		
Code I1	Regs 6, 7, 32– 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
Code I3	Reg 9	Priority identifiers for ecotoxic substances
Code I9	Reg 18	Secondary identifiers for all hazardous substances
Code I11	Reg 20	Secondary identifiers for ecotoxic substances
Code I16	Reg 25	Secondary identifiers for toxic substances
Code I17	Reg 26	Use of generic names
Code I18	Reg 27	Requirements for using concentration ranges
Code I19	Regs 29 – 31	Additional information requirements, including situations where substances are in multiple packaging
Code I21	Regs 37- 39, 47- 50	General documentation requirements
Code I23	Reg 41	Specific documentation requirements for ecotoxic substances
Code I28	Reg 46	Specific documentation requirements for toxic substances
Code I29	Regs 51, 52	Signage requirements

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Table J.3: Additional controls for 'water dispersible granule or wettable powder containing 750 g/kg quintozene'

Additional controls for 'Water dispersible granule or wettable powder containing 750 g/kg quintozene'	
3	Application onto or into water
	(1) No hazardous substance described in Schedule 1 may be applied onto or into water.
	(4) In this clause, water means water in all its physical forms, whether flowing or not, and whether over or under ground, but does not include water in any form while in a pipe, tank or cistern.

Non-HSNO Act controls

Agricultural Compounds and Veterinary Medicines Act 1997

Before they can be used, formulations meeting the definition of "agricultural compound" under the Agricultural Compounds and Veterinary Medicines Act 1997 must be approved by the Agricultural Compounds and Veterinary Medicines Group (ACVM Group) of the New Zealand Food Safety Authority. The relevant current registration for quintozene is:

- Terraclor 75WP Reg No. P002215

The ACVM Group imposes controls (referred to as conditions) on the use quintozene formulations under the ACVM Act. The generic conditions applied by the ACVM Group to the substances are listed on the ACVM web site; the following specific conditions have been set by ACVM Group.

Table J.4: Agricultural Compounds and Veterinary Medicines Group conditions for Terraclor 75WP (P002215)

ACVM conditions and obligations	Description
2	The product must be manufactured in accordance with the ACVM Standard for Good Manufacturing Practice and to the chemistry and manufacturing specifications provided by the registrant and approved as part of the registration.
3	Plant Compound: In addition to any labelling, advertising or promotion requirements specified in the current registration, labelling, advertising or promotion of the product must comply with the current ACVM - New Zealand Labelling and Advertising Guide for Plant Compounds Requiring Registration.
6	The product must not be used on any plant or in any manner specifically prohibited in the current registration.
8	If the product is used on any food producing plant or on or around any plant not used to produce food: • Other than those specified on the current registration; or • in a manner not specified in the current registration,

ACVM conditions and obligations	Description
	the user must ensure that residues of any substance in the product that may occur in plant material produced from the plants treated, or in animal material produced from grazing or direct feeding of the plants treated to food producing animals, do not exceed the lesser of either: • the specified residue limit in the current New Zealand (Maximum Residue of Agricultural Compounds) Food Standard and any subsequent amendments; or • the default maximum residue limit in the current New Zealand (Maximum Residue of Agricultural Compounds) Food Standard and any subsequent amendments, when a maximum residue limit for that substance has not been specified.
37	Ongoing obligations: The registrant must provide an annual summary of adverse events to the ACVM Group. Adverse events which have serious implications for the continued use of the product must be notified immediately. The registrant must also advise the ACVM Group of any new studies or data that contradict information previously supplied.

Appendix K: Parties involved during the preparation of the application

Agricultural Compounds and Veterinary Medicines Group (ACVM) of the New Zealand Food Safety Authority (NZFSA)

Bloomz New Zealand Limited

Fruit Fed Supplies

Hort Fert Plus Limited

New Zealand Sports Turf Institute

Nufarm

Nursery and Garden Industry Association

Plant and Food Research

Van Lier Nurseries Ltd

Appendix L: References

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[27] Pentachloronitrobenzene (PCNB) is a synonym for quintozene.

Confidential Appendix M: Dioxin content of Terraclor 75WP

Confidential Appendix N: Human Exposure and Risk Assessment for Dioxin