Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

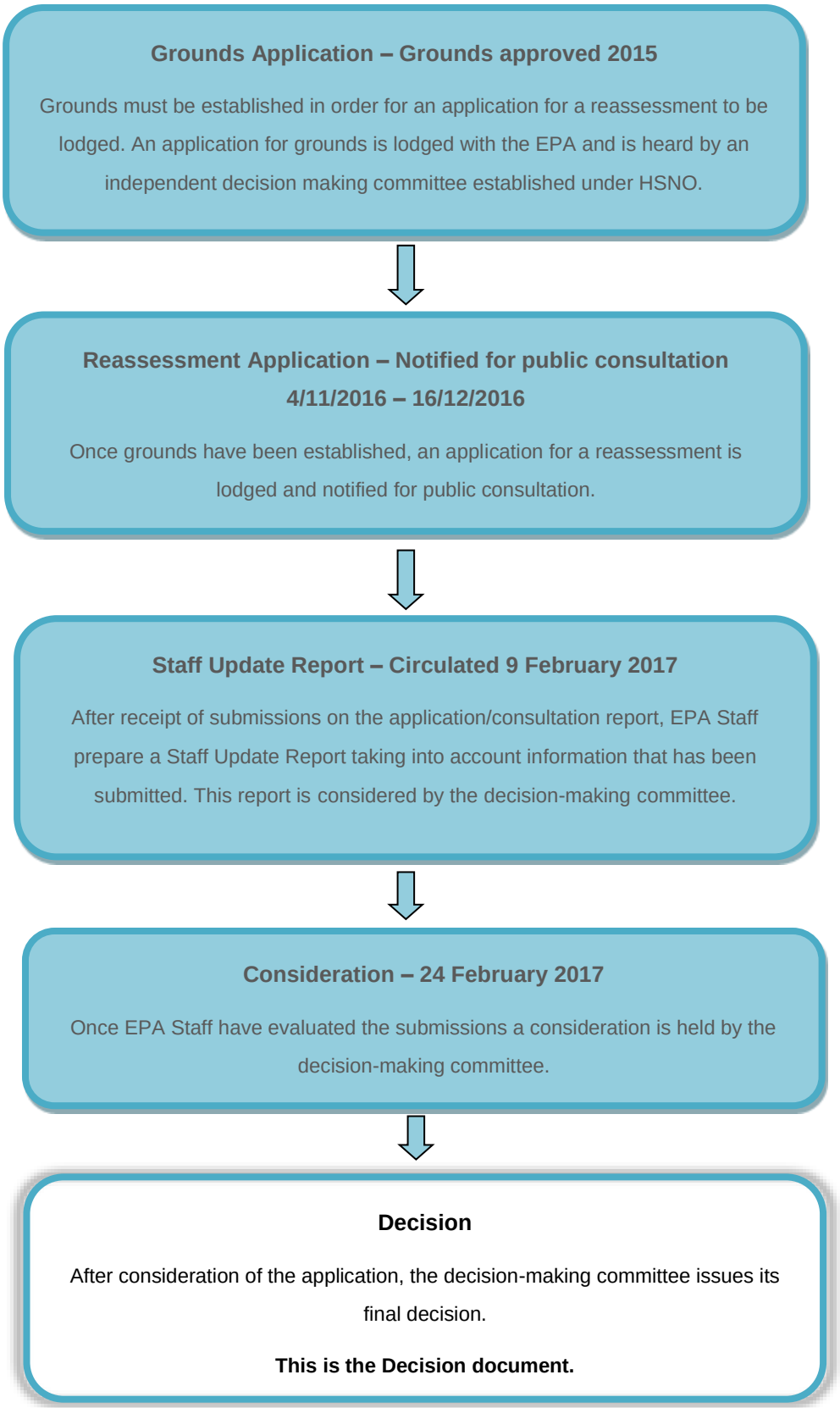
Application for the reassessment of a hazardous substance

Under sections 63 and 63A of the Hazardous Substances and New Organisms Act 1996

6 April 2017

	Chlorothalonil-containing formulations reassessment
Application code	APP202349
Application type	The reassessment of a hazardous substance under sections 63 and 63A of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Application sub-type	Notified – Chief Executive initiated Reassessment
Applicant	Environmental Protection Authority
Purpose of the application	To reassess five chlorothalonil-containing formulations used as home-garden fungicides
Date application received	25 October 2016
Submission period	4 November 2016 - 16 December 2016
Hearing date	24 February 2017
Consideration period	24 February 2017 to 6 April 2017
Considered by	Dr Kerry Laing – Chair Dr John Taylor Dr Sharon Adamson

Overview of the reassessment process:



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Summary

1. The application was prepared by the staff of the EPA on behalf of the Chief Executive, who initiated this reassessment.

2. During the submission period, nine submissions were received on the application. Eight submissions supported the application and one opposed the application. Four submitters requested to speak to their submissions at a hearing. Several submitters recommended that one substance (approval number HSR000618) should be revoked from use by professional as well as non-professional users.

3. The Grounds for Reassessment were only established for the risks of chlorothalonil-containing products during home (non-professional) use. The risks from professional/workplace use of chlorothalonil-containing products were out of the scope of the present application. In order to revoke approval for professional use of substances under HSR000618, new Grounds for Reassessment would need to be undertaken for the risks associated with professional use.

4. The outcome of the reassessment is summarised in the following table.

Table 1: Summary of reassessment decision

Substances for reassessment	HSNO Number	Approval - Decision
Suspension concentrate containing 500 g/L chlorothalonil (Substance B) (trade name Yates Bravo)	HSR000480	Declined: Revoke approval – disposal of existing stocks within six months of the disposal notice coming into force on 11 May 2017, as published in the Gazette.
Suspension concentrate containing 102 g/L chlorothalonil and 125 g/L thiophanate methyl (trade name Yates Greenguard)	HSR000147	Declined: Revoke approval – disposal of existing stocks within six months of the disposal notice coming into force on 11 May 2017, as published in the Gazette.
Suspension concentrate containing 62.5 g/L chlorothalonil, 9.6 g/L tau-fluvalinate and 62.5 g/L thiophanate methyl (trade name Yates Guardall)	HSR000586	Declined: Revoke approval – disposal of existing stocks within six months of the disposal notice coming into force on 11 May 2017, as published in the Gazette.
Suspension concentrate containing 250 g/L chlorothalonil and 250 g/L thiophanate methyl (trade names: 1, McGregor's Black Spot and Fungus Spray; 2, Watkins Fungus and Mildew Spray)	HSR000618	Approved: Change classifications and add additional controls to prevent the non-professional use of this substance in the home, but allow the use in a workplace setting – non-professional use to be phased out within 6 months. Manufacturers, importers and must re-label and revise classifications and controls as soon as practicable and by 6 April **2018** at the latest. For suppliers: Products supplied after 6 April **2018** must be labelled as required by the new classifications and controls.
Tui Disease Eliminator (ready to use) containing 1.5g/L chlorothalonil	HSR100872	Declined: Revoke approval – disposal of existing stocks within six months of the disposal notice coming into force on 11 May 2017, as published in the Gazette.

1. Background

1.1. Scope

1.1.1. Chlorothalonil is a broad spectrum, a non-systemic pesticide commonly used as a fungicide to control fungal foliar diseases in vegetables, turf and ornamental crops. It is used in commercial agriculture and home gardens as well as golf courses and other grassed sporting surfaces. Chlorothalonil is also used as a wood protectant.

1.1.2. Chlorothalonil is acutely toxic (particularly following inhalation) and there are concerns over the potential for chlorothalonil to cause longer term adverse health effects in humans. It is also corrosive to the eyes and causes contact sensitisation. Chlorothalonil is classified as a suspected carcinogen to humans, based on findings of kidney tumours in male rats and mice and in female rats following administration in long-term toxicity studies.

1.1.3. Regulatory reviews of chlorothalonil in the US, Canada, and the European Union have identified concerns regarding acute and chronic health effects on people which have resulted in the prohibition of certain uses of chlorothalonil (including non-professional use) and/or the introduction of stringent risk mitigation measures for professional use.

1.1.4. The Environmental Protection Authority (EPA) has reassessed the approvals of substances containing chlorothalonil used as home-garden (non-professional) fungicides (APP202349) because of issues identified in the reassessment of anti-fouling paints and the assessment of an application for an alternative product containing chlorothalonil for non-professional use. One of the substances (HSR000618) included in this reassessment is also used in a professional setting. However, as the Grounds for Reassessment was only established for risk from home use, the risks from professional use have not been considered in this application.

1.2. Purpose of this document

1.2.1. This document has been prepared by the Decision-Making Committee (the Committee) for this application. It outlines the reassessment of the available information and notifies our decision on the use of substances containing chlorothalonil covered in this application.

2. The reassessment of five chlorothalonil substances

2.1. Grounds

2.1.1. The Environmental Protection Authority (EPA) completed a group reassessment of antifouling paints in 2013, which included paints containing chlorothalonil. During this reassessment (APP201051) the classifications of chlorothalonil were reviewed and a number of changes were identified. This led to grounds being established to reassess the classification of the other chlorothalonil-containing substances that are approved under the Act.

2.1.2. Subsequently, the EPA received an application for a non-professional fungicide containing chlorothalonil (APP202057). The assessment of this application identified that there were likely to be unacceptable human health risks from the use of this substance and that these risks could not be mitigated through the application of controls. This application was therefore declined by the EPA.

2.1.3. Based on this decision and the new information relating to the risks from non-professional use of chlorothalonil-containing substances in the home garden, the Grounds were established to reassess the five existing chlorothalonil-containing formulations that are used as non-professional fungicides.

2.2. Substances and approvals for reassessment

2.2.1. There are five approvals in total covered by this reassessment, pertaining to chlorothalonil-containing formulations used as non-professional fungicides. They are traded under the following approvals and names:

- HSR000480 Yates Bravo
- HSR000147 Yates Greenguard
- HSR000586 Yates Guardall
- HSR000618 McGregor's Black Spot and Fungus Spray; and Watkins Fungus and Mildew Spray
- HSR100872 Tui Disease Eliminator for Fruit & Veges.

2.3. The application

2.3.1. The application for reassessment was prepared by EPA staff on behalf of the Chief Executive under section 63 and section 63A of the Act.

2.3.2. The application highlighted assumptions included in the original risk assessments of these products, as well as significant data gaps that had introduced uncertainty to the original assessments. It was noted in the application that additional information addressing these areas might allow for further refinement of the risk assessments. However, no information was provided to the EPA during the submission process to refine the risk assessment.

2.3.3. Updated compositional information (including impurities and source of active ingredient) for the five chlorothalonil-containing formulations was sought from the manufacturers but this was not received.

2.4. Legislative basis for the application

2.4.1. The application for the reassessment was lodged pursuant to section 63 of the Act for substances HSR000480, HSR000147, HSR000586, and HSR100872 and section 63A of the Act for substance HSR000618 and, as required under those sections, deemed to be an application made under the Act.

2.4.2. For those reassessments undertaken under section 63, section 29 requires the Committee to take into account any controls which may be imposed on the substance, all effects of the substance during its lifecycle, and the likely effects of the substance being unavailable and to make a decision based on whether the positive effects of the substance outweigh the adverse effects of the substance.

2.4.3. For the reassessment undertaken under section 63A, the Committee must consider all the effects associated with the reassessment, and the best international practices and standards for safe management of hazardous substances, and then decide whether to vary controls on the hazardous substance, and/or the description of the hazardous substance.

2.4.4. Consideration of the application followed the relevant sections of the Act and the decision-making Methodology established under section 9 of the Act.

2.5. Appointment of the Committee

2.5.1. The Committee were appointed in accordance with the Crown Entities Act 2004 to consider the application in accordance with a delegation under section 19(2)(b): Dr Kerry Laing (Chair), Dr John Taylor and Dr Sharon Adamson.

2.6. Timeline

2.6.1. The timeline for the application was as follows:

Table 2: Application timeline

Action	Date
Application formally received	25 October 2016
Application publicly notified	4 November 2016
Public submissions closed	16 December 2016
Staff Update Report circulated	9 February 2016
Consideration held	24 February 2017 – 6 April 2017

2.7. Notification of the application

2.7.1. The application was formally received on 25 October 2016.

2.7.2. In accordance with section 53 of the Act, the application was publicly notified on the EPA website on 4 November 2016.

2.7.3. The Minister for the Environment was advised of the application on 4 November 2016 in accordance with section 53(4) (a) of the Act.

2.7.4. An application summary was also sent to government agencies that were identified as having a specific interest in the application, and interested parties who had previously indicated that they wished to be notified of this application in accordance with section 53(4)(b) of the Act.

2.8. Public consultation and submissions

2.8.1. Nine submissions were received during the public notification period; eight supported the proposals outlined in the application and one opposed the proposals.

Table 3: Submissions received

Submission Number	Submitter	Submitter Organisation (if relevant)
120779	George Holt	
121279	Bruce Scanlon	
122292	Susan Collier	WorkSafe New Zealand
122327	Claire Bleakley	
123371	Represented by Don MacLeod	Apicultural Industry Technical Focus Committee
123372	Mischa Davis	The Soil & Health Association
123373	Charles Nathan	Te Puna Kaitiaki oo Rawene & Ngapuhi HSNO Komiti
121442	Oliver Sutherland	Te Rūnanga o Ngāi Tahu (Ngāi Tahu)
123443	Anthony Bellve	Waikato Domestic Beekeepers' Association

2.8.2. Key points from the submissions are addressed throughout the remainder of this document.

2.9. Staff Update Report

2.9.1. EPA staff prepared a Staff Update Report to provide the Committee and submitters with a review of the submissions received in response to the public notification of the reassessment application and the EPA responses to significant issues raised.

2.10. Information available for the consideration

2.10.1. A consideration meeting was convened in accordance with section 60 of the Act and clause 2(b) of the HSNO Methodology. The consideration was held following the hearing on 24 February 2017.

2.10.2. The Committee considered that it had received sufficient information to proceed with its consideration of the application including the following:

- Reassessment application
- Staff Update Report
- Nine written submissions
- Information presented at the hearing.

3. Treaty of Waitangi (Te Tiriti ō Waitangi)

3.1.1. Under section 8 of the Hazardous Substances and New Organisms Act (1996), all persons exercising powers and functions under the Act are to consider the principles of the Treaty of Waitangi (Tiriti ō Waitangi).

3.1.2. In reference to the principles of the Treaty of Waitangi, the Committee focused its attention on the generally accepted principles of partnership, participation, and protection.

3.1.3. The principles of partnership and participation refer to the shared obligation on both the Crown and Māori to act reasonably, honourably and in good faith towards each other to ensure the making of informed decisions on matters affecting the interests of Māori. Additionally, the Waitangi Tribunal has previously recommended that "Environmental matters, especially as they may affect Māori access to traditional food resources also require consultation with Māori people concerned."

3.1.4. The Crown's duty of active protection is the obligation to take positive steps to ensure Māori interests are protected. Further, that this protection 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.

4. Response from submitters

4.1. Introduction

4.1.1. The Committee considered all nine submissions received. They were detailed in the EPA Staff Update Report. Full submissions are available on the EPA website.

4.1.2. Several submitters also recommended that the use of all chlorothalonil-containing substances should be reassessed and recommended the revocation of Approval HSR000618 for both professional and non-professional users. However, the risks from professional use of chlorothalonil-containing products were out of the scope of the application.

4.1.3. Several submitters recommended that the EPA conduct a full quantitative environmental exposure and ecological risk assessment for chlorothalonil and apply those findings to the present controls for all existing and future uses. However, the EPA responded that the human health risks alone are sufficiently high to justify prohibiting non-professional use, precluding the need for an environmental risk assessment in this setting.

4.1.4. Two submitters provided information on the adverse effects on the environment, specifically the effects on fish, aquatic invertebrates, and amphibians. The Committee is aware of the toxicity of chlorothalonil, and the information did not affect the assessment, as it was focussed only on human health.

4.1.5. The Committee noted the concerns of the WorkSafe New Zealand submission stating that international experience with risk mitigation measures for professional use of chlorothalonil suggests that usage patterns of chlorothalonil in New Zealand may result in risks not managed by the default HSNO controls. Consequently, WorkSafe New Zealand called for the 'EPA to consider reassessing the professional use of chlorothalonil'.

4.2. The Hearing

EPA Staff Presentation

4.2.1. Jeane Nicolas, EPA Advisor HS Applications, presented a summary of the application and Staff Update Report. It covered the background as the basis for Grounds of this reassessment and its scope and methodology for the exposure risk assessment models, as well as comments on the submissions and the Staff Recommendation.

4.2.2. From the application, Jeane noted that in the European Union chlorothalonil is banned in consumer products. The US EPA has concerns about chlorothalonil regarding residential exposure by inhalation and there have been revised occupational/residential exposure and risk assessments. In Canada, further risk reduction measures have been included in product labels – around additional personal protective equipment, restricted entry intervals, and restricting the maximum application rates on golf courses.

4.2.3. Jeane Nicolas outlined the stages of the risk assessment that were detailed in the application. The EPA exposure assessment models are based on exposure estimates and the control measures necessary to manage this potential risk for human contact. These were represented by the Operator (e.g. the consumer buying the product and using it at home), the Bystander (e.g. children), and the Re-entry worker (consumer re-entering the treated area).

4.2.4. The summary risk reassessment results were:

- risks to operators/consumers are not acceptable
- risks for re-entry at twenty-four hours without gloves are not acceptable
- re-entry interval without gloves is between 26 to 70 days, (dependent on activity)
- the risks to a small child or toddler (bystander) are not acceptable
- based on the substance classifications, personal protective equipment (PPE) is recommended – protective gloves and eye protection.

4.2.5. The EPA performed a qualitative review of other active ingredients present in the substance included in the reassessment, namely thiophanate methyl (present in HSR000147, HSR000618 and HSR000586) and tau-fluvalinate (HSR000586). They concluded that exposure to chlorothalonil from non-professional use of these products poses greater human health risks than exposure to the thiophanate methyl and tau-fluvalinate in the products.

4.2.6. Jeane Nicolas noted that the submissions provided information and recommendations on a range of environmental impacts that chlorothalonil poses due to its toxicity.

4.2.7. The EPA acknowledges that there are effects on fish, aquatic invertebrates, amphibians, and bees. However, it was not necessary to assess the potential of these effects, as human health risks alone were sufficiently high enough to justify prohibiting chlorothalonil for non-professional use.

4.2.8. Jeane Nicolas concluded that none of the additional information received by the EPA within the submission period altered the Staff recommendations to the Committee about human health risks.

4.2.9. The Committee queried the EPA on whether the characteristics of toxicity could increase from the multiple actions of chlorothalonil and other active components. The EPA affirmed that this is possible.

4.2.10. The Committee also queried whether the additional controls added to substance HSR000618 for professional use were able to mitigate adequately or prevent the effect on bystanders. The EPA stated that in order to assess the bystander risk under professional use a risk assessment would need to be undertaken.

4.2.11. Another submitter (Apicultural Industry) expressed concern that the residual risk to dermal contact of 26 to 70 days was of concern to the spraying of fruit or vegetables for human consumption, as this

time considerably exceeded the withholding period, after which the produce was deemed safe to be consumed. The EPA reiterated that they had not received any additional information throughout the application process to alter their risk assessment inputs.

Submissions

4.2.12. Four submitters presented on their submissions at a hearing:

- Apicultural Industry Technical Focus Committee
- Waikato Domestic Beekeepers' Association
- Claire Bleakley
- The Soil & Health Association.

4.2.13. Don MacLeod presented for the Apicultural Industry Technical Focus Committee. He stated that chlorothalonil is a significant substance of use in New Zealand and in his 'guess' its home (non-professional) use of the product amounted to only 10% of its production, the balance of 90% is for commercial use – a lot of it is still going to be used. 'That is our concern, for bees'

4.2.14. Mr MacLeod considered the scope of the assessment was too limited, focusing only on human health risks and excluding effects on bees. The major risk to bees occurs when spraying, while plants and trees were in flower. He suggested to the Committee that extra labelling comments about the effects on bees during flowering could be added.

4.2.15. He also voiced concern about the fact that the Ministry for Primary Industries has 23 registered chlorothalonil-containing substances and that this assessment only concerned five products. The Apicultural Industry Technical Focus Committee recommended to the Committee that professional use HSR000618 also should be revoked and that the professional use of other chlorothalonil-containing products also should be reassessed.

4.2.16. The Committee emphasized that this reassessment was bound by its scope relating to non-professional use. It stated that the primary concern for the EPA in this application was human health first and recognised that other substances also need to be assessed, but had to be done within EPA's programme and prioritisation of resources to complete assessments.

4.2.17. Claire Bleakley represented herself and was concerned about any exposures of chlorothalonil to adolescents and toddlers. She gave the example of fruit picking, where young adults during summer jobs could be exposed to the chemicals applied in a professional setting that could have long-term health effects. She, therefore, implored the Committee to also reassess chlorothalonil-containing products for professional use.

4.2.18. Cameron Blackbourn and Anthony Bellve presented for the Waikato Domestic Beekeepers (by Skype). Their presentation detailed emerging research from the Ministry for Primary Industries about the causes of beehive losses across New Zealand. They noted the importance of bees in food production and indicated that their decline in numbers was of global concern.

4.2.19. They strongly recommended the EPA revoke the approval of HSR000618, for both professional and non-professional use and further recommended, as a matter of urgency, the reassessment of other chlorothalonil-containing products for professional use.

4.2.20. Mischa Davis, representing The Soil and Health Association, stated their concerns about the cumulative and synergistic effects of chlorothalonil and the other actives in the products, and their effect on the environment. The EPA in reply stated that all components of the formulations were assessed in the hazard assessment and the presences of multiple active ingredients in the formulation were assessed quantitatively.

4.2.21. The Committee Chair concluded the hearing by thanking the submitters and noted that the information was helpful to the Committee's thought processes – if not necessarily aligned with the application scope.

5. Hazard classifications of chlorothalonil-containing substances

5.1.1. The following classification changes were proposed by the EPA staff for HSR000618. The Committee has adopted the classifications listed in Table 4.

Table 4: Summary of chlorothalonil-containing fungicide substances that should be assigned the following hazard classifications (bold text denotes changes to the current classifications)

Substance name	Approval number	Current classification	Recommended Classification
Suspension concentrate containing 250 g/L chlorothalonil and 250 g/L thiophanate methyl	HSR000618	6.1B(inhalation), 6.4A, 6.6B, 6.7B, 6.9A (All), 9.1A, 9.2B, 9.3C	6.1B (inhalation), **6.3B, 8.3A, 6.5B,** 6.6B, 6.7B, 6.9A (oral), 9.1A, **9.2C,** 9.3C

6. Assessment of benefits

6.1. Summary

6.1.1. The Committee's view, set out in more detail below, is that the benefits from substances containing chlorothalonil are outweighed by the risks for non-professional use.

6.1.2. The Committee reviewed the EPA staff assessment of the potential benefits of all the substances containing chlorothalonil listed in the application.

6.1.3. Chlorothalonil is a broad-spectrum, contact, and protectant fungicide with long residual activity. The diversity of use is a key benefit for non-professional use. The Committee noted that there are alternative fungicides available with lower hazards.

6.1.4. The Committee had no information presented to them which could inform the level of non-professional use. Consequently, an assessment on dependency by consumers on chlorothalonil products and any potential impacts of withdrawal was not able to be made.

6.2. Human health benefits

6.2.1. The Committee considered that there are no human health benefits to be derived from the use of chlorothalonil-containing products used in the non-professional settings.

6.3. Benefits to Māori

6.3.1. No specific benefits to Māori have been identified.

6.4. Benefits to society and communities

6.4.1. The Committee recognised that home gardening is a popular activity in New Zealand, as well as playing sport on turf, which has a positive effect on society and communities in terms of health and well-being. The need to be able to quantify this effect versus cost of use requires research with information that is not readily available.

6.4.2. The Committee noted the EPA comments that the level of indirect benefit to public health through the use of chlorothalonil is estimated to be minimal.

7. Assessment of adverse effects

7.1. Hazard assessment

7.1.1. Chlorothalonil is highly acutely toxic to humans following inhalation. It is also corrosive to the eyes and causes contact sensitisation. Chlorothalonil is classified as a suspected carcinogen to humans, based on findings of kidney tumours in male rats and mice and in female rats following administration in long-term toxicity studies.

7.2. Risk assessment

7.2.1. The Committee noted the EPA Staff conducted a quantitative human health risk assessment for chlorothalonil-containing products used in non-professional settings in New Zealand and provided qualitative comment on environmental risk.

7.2.2. To allow a comparison between the benefits and the risks associated with the application of chlorothalonil substances, qualitative descriptors were used which assign the level of risk into broad categories of negligible, low, medium or high. In line with the HSNO Methodology, these descriptors account for the likelihood and magnitude of an adverse effect.

7.2.3. Full details on the risk assessment approach and results can be found in the application.

7.2.4. The Committee noted that the application had highlighted assumptions included in the original risk assessments of these products, as well as significant data gaps that had introduced uncertainty to the original assessments. It was also noted that the EPA did not receive any additional information during the submission process that may allow for further refinement of the risk assessments.

7.3. Adverse effects on human health

7.3.1. The Committee considered the effects on human health outlined in the application. The Committee noted that the quantitative human health risk assessment showed the risks to operators, bystanders, and any person re-entering the treated area, are greater than the level of concern for spray application for all products.

7.3.2. The Committee considered that the risks to human health to be non-negligible for non-professional use of chlorothalonil-containing products.

7.4. Adverse effects on the environment

7.4.1. On the basis of the high human health risks, and as no controls could mitigate the human health risk of chlorothalonil-containing products use in non-professional settings, no quantitative environmental risk assessment was performed.

7.5. Adverse effects on the relationship of Māori to the environment

7.5.1. Chlorothalonil presents a significant potential risk to Māori in terms of adversely affecting taha hauora, including vulnerable groups such as tamariki (children) and kaumātua (the elderly).

7.5.2. The use of chlorothalonil raises concerns around how potential harm to taha hauora may manifest in relation to whānau environments and lifestyle contexts. This substance may potentially affect all four cultural health dimensions of taha hauora. The availability of chlorothalonil may not engender an overall net benefit for kaitiakitanga.

8. International obligations

8.1.1. To achieve the purpose of the HSNO Act, the EPA must consider the impacts of the application on New Zealand's international obligations.

8.1.2. On the basis of the EPA's analysis, the Committee considered that accepting their recommendations on the reassessment would not impact on any of New Zealand's international obligations.

9. Overall evaluation of effects

9.1. Introduction

9.1.1. Pursuant to section 29 of the Act, the Committee considered the reassessment of the hazardous substance approvals HSR000480, HSR000147, HSR000586, and HSR100872 with respect to section 63. The reassessment of HSR00618 was undertaken under section 63A. In doing so, the Committee applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology").

9.1.2. Clause 34 of the Methodology sets out the approaches available to the Authority in evaluating the combined impact of risks, costs and benefits i.e. weighing up the risks, costs, and benefits.

9.2. Summary and conclusions

9.2.1. The Committee considered that exposure to chlorothalonil as a consequence of non-professional use in New Zealand represents an unacceptable risk to people (operators) and bystanders (e.g. children) and through re-entry.

10. Recommendation

10.1.1. The Committee noted that the risk to bystanders and re-entry workers exposed to chlorothalonil as a consequence of non-professional use may apply equally to bystanders and re-entry workers exposed to chlorothalonil as a consequence of its professional use. Examples of potential risk scenarios are the exposure to children playing on municipal sports fields sprayed with chlorothalonil by council contractors or fruit pickers in a commercial orchard in which trees have been sprayed with chlorothalonil. The Committee also noted the concerns of submitters on the potential environmental risks associated with the use of chlorothalonil-containing products.

10.1.2. The Committee notes that the reassessment of chlorothalonil-containing products has been on the EPA reassessment programme for some time and strongly recommends that the EPA, as a matter of urgency, reassess professional use of chlorothalonil-containing products.

11. Decision

11.1.1. Pursuant to Part 2 of the Act, and to sections 63 and 29, and 63A of the Act, the Committee has considered this application to reassess five chlorothalonil-containing formulations used as non-professional use plant protection fungicides.

11.1.2. Based on consideration and analysis of the information provided, and in accordance with the Act and the Methodology, the Committee is satisfied, for the reasons set out in this decision, that the positive effects (benefits) associated with the use of the substances covered in this application for non-professionals do not outweigh the adverse effects (risks and costs).

11.1.3. The Committee notes that it has made its assessment solely on human health risks, as the application was only in the context of non-professional use and because the human health risks were deemed to be unacceptable and unable to be mitigated, no other types of risk needed to be considered in order to come to a decision. Further, overseas environmental regulators have restricted or banned the substance for non-professional use. The Committee also considered the likely effects of the substances being unavailable and declines the applications for home use and that for these four substances – approvals are revoked.

HSR000480, HSR000147, HSR000586, HSR100872

11.1.4. The Committee has decided that for these revocations, the decision will take effect on 11 May 2017 after a notice issued in accordance with section 66 of the Act is published in the Gazette ("the commencement date"). That notice specifies controls relating to disposal of the substances within six months.

11.1.5. The Committee retains the approval; with significant restrictions for substance HSR000618 to prevent the use of this substance outside of the workplace. New controls apply to approval number HSR000618; these are listed in Appendix A of the decision and these will apply from 11 May 2017.

11.1.6. The effect of this decision is that:

- import/manufacture of products under approvals (HSR000480, HSR000147, HSR000586, HSR100872) are no longer authorised on the commencement date of the decision
- use of these substances is prohibited six months after the commencement date and disposal must occur within six months from the commencement date
- products manufactured and imported under HSR000618 must be relabelled to take account of new controls as soon as practicably possible and by the 6 April 2018 at the latest.

Dr Kerry Laing	**Date: 6 April 2017**
Chair, Decision Making Committee **Environmental Protection Authority**	

Appendix A: Controls applying to suspension concentrate containing 250 g/litre chlorothalonil and 250 g/litre thiophanate methyl (HSR000618)

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description *(including variations and explanatory notes)*
T1	Regs 11 – 27	Limiting exposure to toxic substances through the setting of TEL, ADE and PDE values No TEL values are set for any component of this substance at this time.
T2	Regs 29, 30	Controlling exposure in places of work through the setting of WESs. *Variation:* *The Authority adopts as Workplace Exposure Standards for this substance, and each component of this substance, any applicable value or values specified in the document described in the 7th Edition of "Workplace Exposure Standards and Biological Exposure Indices".*
T3	5(1), 6	Requirements for keeping records of use
T4	Reg 7	Requirements for equipment used to handle substances
T5	Reg 8	Requirements for protective clothing and equipment
T6	Reg 9	Approved handler/security requirements for certain toxic substances Variation: **9A Exception to approved handler requirement for transportation of packaged pesticides** (1) Regulation 9 is deemed to be complied with if: (a) when this substance is being transported on land— (i) by rail, the person who drives the rail vehicle that is transporting the substance is fully trained in accordance with the approved safety system for the time being approved under section 6D of the Transport Services Licensing Act 1989; and (ii) other than by rail, the person who drives, loads, and unloads the vehicle that is transporting the substance has a current dangerous goods endorsement on his or her driver licence; and (iii) in all cases, Land Transport Rule: Dangerous Goods 1999 (Rule 45001) is complied with; or when this substance is being transported by sea, one of the following is complied with: (i) Maritime Rules: Part 24A – Carriage of Cargoes – Dangerous Goods (MR024A): (ii) International Maritime Dangerous Goods Code; or (c) when this substance being transported by air, Part 92 of the Civil Aviation Rules is complied with. (2) Sub clause (1)(a)— (a) does not apply to a tank wagon or a transportable container to which the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 applies; but (b) despite paragraph (a), does apply to an intermediate bulk container that complies with chapter 6.5 of the UN Model Regulations.
Code	**Regulation**	**Description *(including variations and explanatory notes)***

		(3) Sub clause (1)(a)— (a) does not apply to a tank wagon or a transportable container to which the Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 applies; but (b) despite paragraph (a), does apply to an intermediate bulk container that complies with chapter 6.5 of the UN Model Regulations. (4) Sub clause (1)(c)— (a) applies to pilots, aircrew, and airline ground personnel loading and managing this substance within an aerodrome; but (b) does not apply to— (i) the handling of this substance in any place that is not within an aerodrome; or (ii) the loading and managing of this substance for the purpose of aerial spraying or dropping. (5) In this regulation, UN Model Regulations means the 19th revised edition of the Recommendation on the transport of Dangerous Goods Model Regulations, published in 2015 by the United Nations. The following regulation is inserted immediately after regulation 9A: **9B Exception to approved handler requirement for aerial application of certain substances** Regulation 9 is deemed to be complied with if, in the case of the aerial application of a hazardous substance, the person who carries out the application has a current pilot chemical rating in accordance with Part 61 of the Civil Aviation Rules.
T7	Reg 10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles
E1	Regs 32 – 45	Limiting exposure to ecotoxic substances through the setting of EELs *Variation:* *No EEL values are set at this time and the default EELs are deleted*
E2	Regs 46 – 48	Restrictions on use of substances in application areas
E5	Regs 5(2), 6	Requirements for keeping records of use
E6	Reg 7	Requirements for equipment used to handle substances
E7	Reg 9	Approved handler/security requirements for certain ecotoxic substances Variation: See control T6

Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description
I1	Regs 6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability
I2	Reg 8	Priority identifiers for corrosive substances
I3	Reg 9	Priority identifiers for ecotoxic substances
I8	Reg 14	Priority identifiers for toxic substances

I9	Reg 18	Secondary identifiers for all hazardous substances
I10	Reg 19	Secondary identifiers for corrosive substances
I11	Reg 20	Secondary identifiers for ecotoxic substances
I16	Reg 25	Secondary identifiers for toxic substances
I17	Reg 26	Use of generic names
I18	Reg 27	Requirements for using concentration ranges
I19	Regs 29 – 31	Additional information requirements, including situations where substances are in multiple packaging
I20	Reg 36(8)	Durability of information for class 6.1 substances
I21	Regs 37 – 39, 47 – 50	General documentation requirements
I22	Reg 40	Specific documentation requirements for corrosive substances
I23	Reg 41	Specific documentation requirements for ecotoxic substances
I28	Reg 46	Specific documentation requirements for toxic substances
I29	Regs 51, 52	Signage requirements
I30	Reg 53	Advertising corrosive and toxic substances

Hazardous Substances (Packaging) Regulations 2001

Code	Regulation		Description
P1	Regs 5, 6, 7(1), 8	General packaging requirements	This variation takes effect on 6 April 2018
P3	Reg 9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria	This variation takes effect on 6 April 2018
P13	Reg 19	Packaging requirements for toxic substances	This variation takes effect on 6 April 2018
P14	20	Packaging requirements for corrosive substances	This variation takes effect on 6 April 2018
P15	Reg 21	Packaging requirements for ecotoxic substances	This variation takes effect on 6 April 2018
PG2	Schedule 2	Packaging requirements equivalent to UN Packing Group II	This variation takes effect on 6 April 2018
PS4	Schedule 4	Packaging requirements as specified in Schedule 4	This variation takes effect on 6 April 2018

Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description

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

Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description
EM1	Regs 6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge
EM2	Reg 8(a)	Information requirements for corrosive substances
EM6	Reg 8(e)	Information requirements for toxic substances
EM7	Reg 8(f)	Information requirements for ecotoxic substances
EM8	Regs 12 – 16, 18 – 20	Level 2 information requirements for suppliers and persons in charge
EM11	Regs 25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans
EM12	Regs 35 – 41	Level 3 emergency management requirements: secondary containment
EM13	Reg 42	Level 3 emergency management requirements: signage

Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001

Code	Regulation	Description
AH 1	Regs 4 – 6	Approved Handler requirements (including test certificate and qualification requirements) Refer to control code E7

Hazardous Substances (Tracking) Regulations 2001

Code	Regulation	Description
TR1	Reg 4(1), 5, 6	General tracking requirements

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Code	Regulation	Description
Tank Wagon	Regs 4 to 43 as applicable	Controls relating to tank wagons and transportable containers

Additional controls

Code	Section of the Act	Control
Water	77A	This substance must not be applied into or onto water[1]
No Home Use	77A	The substance must not be supplied to any person unless — a) The person provides evidence at the time of supply that the substance is required for use in a workplace;[2] and b) In the relevant circumstances it is reasonable to believe that evidence. This substance must not be used or stored in a place unless it is a workplace.
Maximum impurity	77A	The maximum level of hexachlorobenzene in the active ingredient chlorothalonil is set at 0.04 g/kg. The maximum level of decachlorobiphenyl in the active ingredient chlorothalonil is set at 0.03 g/kg.
Sch 8		Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 applies, with Clause 1 replaced by the following: This Schedule applies to every stationary container system that contains, or is intended to contain the substance.

[1] Where '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 or water used in the dilution of the substance prior to application.

[2] A workplace has the same meaning as the Health and Safety at Work Act 2015

Appendix B: Draft direction under section 66 of the Act

Hazardous Substances (Chlorothalonil Containing Substances Direction Prohibiting Use and Controlling Storage and Disposal) Notice 2017

Pursuant to section 66 of the Hazardous Substances and New Organisms Act 1996 ("the Act"), the Environmental Protection Authority issues the following notice.

N o t i c e

1. Title—

This notice is the Hazardous Substances (Chlorothalonil Containing Substances Direction Prohibiting Use and Controlling Storage and Disposal) Notice 2017.

2. Commencement—

This notice comes into force on **11 May 2017.**

3. Interpretation—

(1) In this notice, words and phrases have the meanings given to them in the Act and in Regulations made under the Act.

(2) In this notice, the following words have the following meanings:

Chlorothalonil means chlorothalonil (CAS Number 1897-45-6).

Substances containing chlorothalonil means any of the following substances:

Suspension concentrate containing 500 g/L chlorothalonil (Substance B) formerly approved under the Act with approval number HSR000480 with the hazard classification 6.1E (oral), 6.3B, 6.4A, 6.5B, 6.7B, 6.9A (All), 9.1A, 9.2B, 9.3B;

Suspension concentrate containing 102 g/L chlorothalonil and 125 g/L thiophanate methyl formerly approved under the Act with approval number HSR000147 with the hazard classification 6.1E (oral), 6.3B, 8.3A, 6.5B, 6.6B, 6.7B , 6.9A (All), 9.1A, 9.2B, 9.3C;

Suspension concentrate containing 62.5 g/L chlorothalonil, 9.6 g/L tau-fluvalinate and 62.5 g/L thiophanate methyl formerly approved under the Act with approval number HSR000586 with the hazard classification 6.1D (inhalation), 8.3A, 6.5B, 6.6B, 6.7B, 6.9B (All), 9.1A, 9.2C, 9.3C; and

Tui Disease Eliminator (ready to use) formerly approved under the Act with approval number HSR100872 with the hazard classification 6.5B, 6.7B, 9.1B.

4. Prohibition on use—

No person may use a substance containing chlorothalonil after **11 November 2017**.

5. Controls on substances containing chlorothalonil until 11 November 2017—

(1) The substances containing chlorothalonil are deemed to have the hazard classifications as specified in the definition in 3(2) of this notice.

(2) The controls set out for the approvals specified in this notice shall apply to the substances containing chlorothalonil.

6. Controls on disposal of substances containing chlorothalonil

(1) All substances containing chlorothalonil must be disposed of by **11 November 2017**.

(2) Substances containing chlorothalonil must be disposed of in accordance with the Hazardous Substances (Disposal) Regulations 2001, excluding regulations 8(1)(b) or 9(1)(b). Therefore, substances containing chlorothalonil must not be disposed of by discharge into the environment.

(3) When stored for the purpose of disposal, substances containing chlorothalonil must not be mixed with any other substances.

Dated at Wellington this 6th day of April 2017.

Dr Kerry Laing for and on behalf of the **Environmental Protection Authority:**

Appendix C: Abbreviations and acronyms

Term	Definition
Acute	Adverse effect that occurs after a single exposure which usually lasts for a short time.
ADE	Acceptable Daily Exposure is the amount of a substance that an individual can be exposed to daily over a lifetime without resulting in an appreciable toxic effect.
ADI	Acceptable Daily Intake is the amount of a substance in food or drinking water that can be ingested daily over a lifetime without an appreciable health risk.
Approved Handler	A person who holds a current test certificate certifying that the person has met the requirements of Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001 in relation to an approved handler for 1 or more hazard classifications or hazardous substances.
Benefit	The value of a positive effect expressed either in monetary or non-monetary terms.
Chronic	Adverse effect that occurs after a repeated exposure and which usually are long lasting and recurring.
Cost	The value of an adverse effect expressed either in monetary or non-monetary terms.
Endpoint	Toxicological or ecotoxicological value used in the risk assessment
Exposure	Human or environmental organism contact with a substance.
HSNO	The Hazardous Substances and New Organisms Act 1996.
Likelihood	The probability of an effect occurring.
Magnitude	Expected level of effect.
MPI	Ministry for Primary Industries
MRL	Maximum Residue Limits restrict the quantity of a given chemical remaining on food product samples, which is acceptable in a specific market.
PDE_{food}	The Potential Daily Exposure for food is the amount of a substance in food which may be ingested daily over a lifetime without resulting in an appreciable toxic effect.
PPE	Personal Protective Equipment including any item of equipment used to protect a person from hazards e.g. safety helmet, goggles, gloves, boots, respirator.
REI	A Restricted Entry Interval is the time which must elapse after application of a substance before entry into the treated area is permitted without use of PPE or Respiratory Protective Equipment.
Risk	The combination of the magnitude of an adverse effect and the probability of its occurrence.