



Environmental
Protection Authority
Te Mana Rauhi Taiao

DECISION

Application for the Reassessment of a Group of Hazardous Substances

under Section 63 of the Hazardous Substances and New
Organisms Act 1996

15 September 2015



APP202097: Dichlorvos and its formulations

Chair's introduction

General – use and effects of dichlorvos in New Zealand

Dichlorvos is a volatile and highly effective organophosphate insecticide used to control a wide range of insect pests across the agricultural, horticultural, biosecurity and public health industries, and in domestic/home settings.

The process

The Committee held a hearing in accordance section 60(c) of the Act, as a number of submitters stated in their submissions that they wished to be heard.

The outcome

The Committee has made a decision which attempts to strike an appropriate balance between allowing the continued use of dichlorvos and its formulations for commercial plant protection purposes while ensuring that the most serious effects are appropriately avoided or managed. Where critical to the agricultural sectors, the Committee concluded its use should be allowed to continue, but with additional controls imposed to ensure the risks to people's health and to the environment from such uses are properly managed.

Final comments

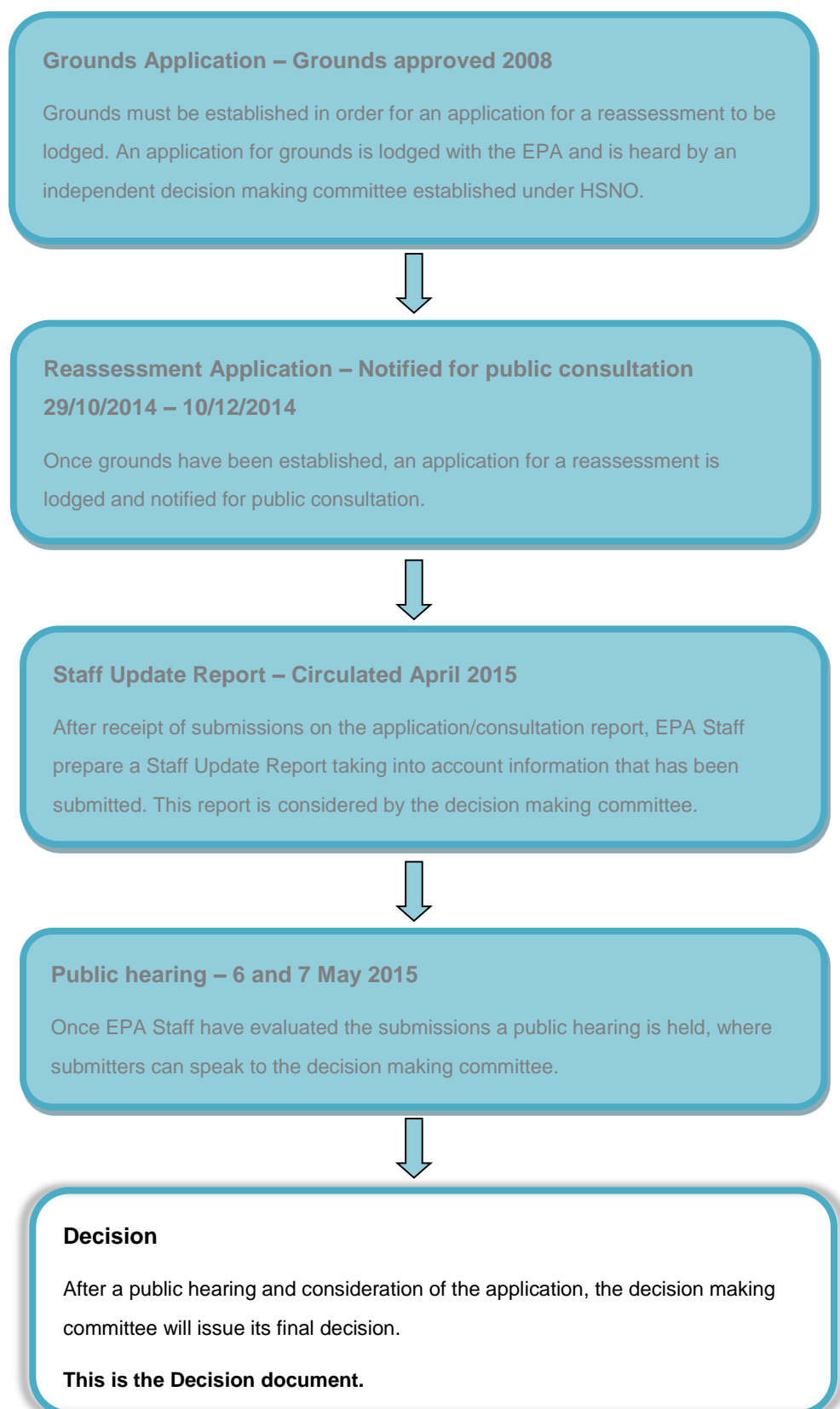
The Committee is mindful of the importance of this decision to all New Zealanders and in particular to the agricultural and horticultural sectors. There is a phase-in period for all the changes to allow time for a change in approach and practice to occur.

Dr Kerry Laing

Chair, dichlorvos and its formulations reassessment committee of the Environmental Protection Authority

15 September 2015

Overview of the reassessment process



1. Summary of decision

Substance	HSNO Approval No.	EPA decision
Dichlorvos [CAS No. 62-73-7] <i>No trade names for this substance</i>	HSR002838	Retain approval
Emulsifiable concentrate containing 1000 g/L dichlorvos <i>Trade name: Nuvos</i>	HSR000211	Retain approval, with significant restrictions
Emulsifiable concentrate containing 1140 g/L dichlorvos <i>Trade name: Divap</i>	HSR000213	Retain approval, with significant restrictions
Aerosol containing 50 g/kg dichlorvos <i>Trade names: Insectigas / ArmourCrop Insecticide</i>	HSR000212	Retain approval, with significant restrictions
Flammable aerosol containing 3.1 g/L dichlorvos and 8.7 g/L propoxur <i>Trade name: BV2 Surface Insecticide</i>	HSR000207	Revoke approval – disposal of existing stocks within six months of decision (prior to 15 March 2016)
Ready-to-use liquid containing 4.4 g/L dichlorvos and 9.6 g/L propoxur <i>Trade name: BV2 Surface Insecticide Bulk</i>	HSR000209	Revoke approval – disposal of existing stocks within six months of decision (prior to 15 March 2016)

2. Background

2.1. Scope

- 2.1.1. The Environmental Protection Authority (EPA) reassessed dichlorvos and five dichlorvos-containing formulations because of concerns about the safety and well-being of people and the environment arising from dichlorvos use.
- 2.1.2. Dichlorvos is a volatile and highly effective organophosphate insecticide used to control a wide range of insect pests across the agricultural, horticultural, biosecurity and public health industries, and in domestic/home settings.
- 2.1.3. Dichlorvos is acutely toxic to humans, with exposure occurring via oral ingestion, dermal absorption, or via inhalation. It is also a potent neurotoxin, inhibiting cholinesterase activity in the blood and brain. The volatile properties of dichlorvos add significantly to the risk profile of dichlorvos-containing substances with the volatilised dichlorvos presenting an inhalation hazard for people applying dichlorvos substances and/or re-entering treated areas. Dichlorvos is also very ecotoxic to aquatic life, birds and bees, and is slightly harmful to soil organisms.

2.2. Purpose of this document

- 2.2.1. This document has been prepared by the Decision Making Committee (the Committee) for this application. It outlines our assessment of the available information, and notifies our decision on the controls and new restrictions on the use of dichlorvos and the formulations covered in this application.

3. The reassessment of dichlorvos and its formulations

3.1. Grounds

3.1.1. In September 2008, the Environmental Risk Management Authority of New Zealand (ERMA New Zealand, now the EPA) established grounds to reassess the approvals for dichlorvos and dichlorvos-containing formulations, in accordance with section 62 of the Act. In reaching that decision, ERMA New Zealand noted the following:

- Overseas regulatory action had led to the withdrawal/phasing out of dichlorvos in Europe (and certain products in North America), the adoption of more stringent measures for domestic and agricultural use in the USA and Canada, and the possible adoption of more stringent measures in Australia.
- The reassessment of dichlorvos and its formulations was aligned with the principles of ERMA New Zealand's Risk Reduction strategy.

3.2. Substances and approvals for reassessment

3.2.1. There are six HSNO approvals in total covered by this reassessment, pertaining to the active ingredient itself (dichlorvos). The substances and approvals covered by this application are detailed in Table 1.

3.3. The application

3.3.1. An application for the reassessment of dichlorvos and its formulations was prepared by EPA staff on behalf of the Chief Executive under section 63 of the Act.

3.3.2. EPA staff sought information from a wide range of sources on the way that the substances are used in New Zealand. The risk assessments were conducted on use patterns as recommended on the product labels and through consultation with industry representatives. These risk assessments and the use patterns evaluated were established during consultation prior to and during the original dichlorvos application (HRC08004: 2010), and included information obtained during the organophosphate and carbamate reassessment undertaken by the EPA between 2012 and 2013.

3.3.3. During these rounds of stakeholder engagement and data gathering, feedback was also sought on the practicality, economic viability and sustainability of proposed additional controls, and on the benefits associated with use of the substances for specific crop sectors.

3.3.4. The Chief Executive submitted the application for reassessment on 24 October 2014.

3.4. Legislative basis for the application

3.4.1. The application for the reassessment was lodged pursuant to section 63 of the Act and, as required under that section, deemed to be an application made under section 29 of the Act. Section 29 requires the decision-making Committee to consider positive and adverse effects

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of the substance and to make a decision based on whether or not the positive effects of the substance outweigh the adverse effects of the substance.

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

3.5. Appointment of the Committee

- 3.5.1. The following members of the HSNO 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, Associate Professor Deborah Read and Mr Damian Stone.

3.6. Timeline

- 3.6.1. The timeline for the application was as follows:

Action	Date
Application formally received	24 October 2014
Application publicly notified	29 October 2014
Public submissions closed	10 December 2014
Staff Update Report circulated	20 April 2015
Hearing held	6 – 7 May 2015

3.7. Waivers

- 3.7.1. Under section 59(5), the Committee waived the following statutory time limits:

- Section 59(1)(c): the requirement to allow 30 working days from the date of public notification for the receipt of submissions, to allow Market Access Solutionz and BOC Ltd additional time to make their submissions;
- Section 59(1)(d): the requirement to fix a date for commencement of the hearing for consideration of the application, being not more than 30 working days after receipt of the application or the closing date for submissions, whichever is the later;
- Section 59(2): the requirement to publically notify its decision as soon as reasonably practicable but not later than 30 working days after the conclusion of the hearing.

- 3.7.2. Before waiving these time periods, the Committee was satisfied that:

- The applicant and the persons making submissions consented to that waiver; or
- Any of those parties who have not so consented would not be unduly prejudiced.

3.8. Notification of the application

- 3.8.1. In accordance with section 53 of the Act, the application was publicly notified on the EPA website on 29 October 2014. Notification was sent to recipients of the relevant interested parties' email lists, and media alerts were issued.
- 3.8.2. The Minister for the Environment was advised of the application on 28 October 2014 in accordance with section 53(4)(a) of the Act.
- 3.8.3. An application summary was also sent to government agencies which 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.

3.9. Staff Update Report

- 3.9.1. 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.
- 3.9.2. In preparing this report, EPA staff reviewed all the submissions and prepared responses to significant issues raised. In response to questions raised in written submissions, EPA staff commissioned a cost benefit analysis by the New Zealand Institute of Economic research (NZIER). Their report was made available to all submitters and formed part of the Committee's information available for the consideration.
- 3.9.3. The Staff Update Report was circulated on 20 April 2015.

3.10. Information available for the consideration

- 3.10.1. The decision-making Committee had available the following for its consideration:
 - Reassessment application and the Staff Update Report
 - Ngā Kaihautū Tikanga Taiao report
 - NZIER cost benefit analysis
 - Dichlorvos and trichlorfon use in New Zealand horticulture (Park et al. 2009)
 - Written submissions
 - Oral submissions made during the hearing

3.11. Public consultation and the hearing

- 3.11.1. In total, 13 public submissions were received on the application, with 10 submitters indicating that they wished to be heard in support of their submissions at a public hearing. Some submissions, such as that from Market Access Solutionz, were from organisations that represented the views of many individuals or agricultural industry sectors.

3.11.2. As a number of submitters had requested to speak to their submission, a hearing was convened in accordance with section 60 of the Act and clause 2(b) of the HSNO Methodology. The hearing was held on the 6 and 7 May 2015 at the Willeston Conference Centre, Wellington.

3.11.3. The hearing was formally closed on 7 May 2015.

3.12. Hearing

3.12.1. The Committee wishes to acknowledge and thank all the submitters for investing significant resources in making their submissions to us. These submissions have greatly assisted us in understanding the issues that arise in relation to the various recommendations we had to consider. In this section of the report the Committee refers specifically to those who presented in person. In doing so, this in no way detracts from those submissions that we received in writing. The Committee wishes to assure all submitters that all of the submissions received have been fully considered as part of this decision.

3.12.2. The Committee heard from a number of organisations and individuals in relation to the use of dichlorvos and its formulations as follows:

- Dr Oliver Sutherland – Ngāi Tahu
- James Whetu – Ngā Kaihautū Tikanga Taiao
- John Hicking – Orion Crop Protection
- Richard Donald
- Ian MacKenzie – Federated Farmers
- Ian Gear – STIMBR and NZGIA
- Nikki Johnson – Market Access Solutionz
- Ben Smith – Tomatoes New Zealand
- Stuart Davis – NZ Squash and Vegetables
- Ian Turk – Persimmon Industry, and
- Nikki Johnson – Asparagus Council

3.12.3. The staff advice was presented at the hearing by Dr Matthew Allen on behalf of the EPA staff team. Other EPA staff team members also provided additional comment or responses to questions from submitters or the Committee.

3.12.4. The Committee heard from John Hicking, who is the technical manager at Orion Crop Protection Ltd. Orion produces *Nuvos*, which is used across many smaller types of crops and in glasshouses because of its unique properties. John stated that he was not aware of any incidents involving the product: *"I find it difficult to reconcile that this stuff is so toxic and*

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has to have all these controls imposed on it, but I've worked for Orion for 11 years ...and we have never received any reports of or incidents relating to the use of Nuvos". However, John welcomed restrictions on uses in houses and offices, and the proposal that it only be used by operators who've been properly trained and take appropriate precautions.

- 3.12.5. In discussing the restrictions EPA staff have proposed on the quantities available for use, John considered that *"15 g per person per day (pppd) ... is not a practical amount. No one operating a commercial glasshouse would be able to take advantage of that"*. He suggested that the Committee consider 1300 g pppd instead of the 15 g pppd for automated equipment in glasshouses as a practical alternative.
- 3.12.6. Richard Donald congratulated the EPA staff on what he considers are appropriate controls that have been proposed. However, he did comment that *"I am surprised that regulations have not been proposed that require neighbours be informed that spraying is happening"*. Furthermore, he expressed doubt that the current Approved Handler certification provided adequate information and monitoring to entrench best practice as normal in New Zealand spray programmes.
- 3.12.7. The Committee noted the need for improved training and clearer guidance on packaging, and considered the best way to enable Approved Handlers to be fully aware of their responsibilities.
- 3.12.8. Ian MacKenzie, who spoke on behalf of Federated Farmers, said *"We acknowledge that dichlorvos is a nasty chemical"*, but he reiterated its unique properties. He explained that storage pests will not go away, and that dichlorvos is being used in the grain industry only to treat infested grain in silos or in post-storage clean up. He considers that dichlorvos, although used in limited quantities, is extremely important to the grain industry. To support this, he highlighted the NZIER cost benefit analysis that shows the high costs associated with withdrawing dichlorvos. However, his main concern was the EPA's recommendation to only allow 15 g pppd as he considers this is insufficient for grain storage treatment.
- 3.12.9. The Committee heard that Federated Farmers had concerns that the EPA would stop or overly limit dichlorvos use. Limiting use would effectively stop use of the product because such small quantities were impractical and it is possible that alternatives would be equally as hazardous.
- 3.12.10. Ian Gear, representing Stakeholders in Methyl Bromide Reduction (StiMBR), and Nursery and Garden Industry Association of New Zealand promoted the need for caution in revoking use of dichlorvos. He requested that any changes to the current regime are informed and science based, and that any alternatives are *"acceptable by our trading partners and our food customers and are actually usable by industry"*.
- 3.12.11. He finished by explaining to the Committee that log export is a significant industry for New Zealand; 55% of timber production is exported as logs. Countries receiving export logs have phytosanitary requirements and StiMBR called for continued use of methyl bromide during

that reassessment. If alternatives to methyl bromide are not effective, dichlorvos may be needed as an ovicide if logs are to be exported. However, he explained that it has not been used in this way, or even trialled yet, and he was not aware of dichlorvos being used overseas in this way.

- 3.12.12. The Committee considered that if dichlorvos could be shown to be an effective alternative to methyl bromide for the fumigation of export logs, and there were sufficient data to show that it could be safely used, then it would be possible to carry out a modified reassessment. This may result in an adjustment to the controls to enable log fumigation to occur.
- 3.12.13. The Committee heard from Nikki Johnson, who spoke to a submission from Market Access Solutionz (MAS) on behalf of numerous small grower industries. Nikki highlighted that dichlorvos has a 1 day pre-harvest interval; meaning food is safe to eat one day after it is sprayed, which is a core component to why this compound is used. She observed that an alternative product is only a true alternative if it can be used with the same time period before produce is able to be consumed.
- 3.12.14. Nikki also discussed off-label use and stated that dichlorvos is registered for treatment of all vegetables so there is no off-label use for vegetables. Some industries which MAS represents, i.e. greenhouse vegetables, outdoor leafy vegetables, squash, brassica, and persimmon, consider the continued use of dichlorvos to be critical. The Committee questioned Nikki specifically about outdoor use, to which she responded that the EPA staff proposals *“are effectively a ban on outdoor use as 15 g pppd is impractical”*.
- 3.12.15. Ben Smith, representing Tomatoes New Zealand (TNZ), showed the Committee a short video of whitefly at a tomato glass house. He discussed the benefits of dichlorvos to his industry by outlining the economic benefits in terms of best case/worst case scenarios. He explained Integrated Pest Management (IPM) and the use of bumblebees for pollination of glasshouse tomatoes. *“Dichlorvos has a great profile ... if you’ve got a lot of whitefly on a given day, you can put that dichlorvos in there and then a day later you can be back introducing beneficial insects. It cuts down on further agrichemical usage”*. He added that there is no effective whitefly control programme in glasshouses without dichlorvos.
- 3.12.16. Ben explained the difference between fogging and spraying of dichlorvos in glasshouses for pest control, and went through the costs associated with each. He offered the semi-automated sprayers with operators in full PPE as a viable alternative. He explained that multiple machines are used so an operator might take ~ 4 hours to spray a greenhouse; and each unit costs ~\$12,000. He indicated that he wanted the quantity limit to be 750-1000 g pppd. Up to 2 kilos are currently applied in a single large glasshouse in a day for the largest greenhouses and operators would use multiple people to apply it.
- 3.12.17. Ben asked the Committee and the EPA staff some questions regarding the exclusion zone. *“Is it proven that there is need for one at all if there is spray in a closed space? Is there a reason 20 meters was chosen and is this for dichlorvos? I put forward 10 meters, thinking*

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again of many of the glasshouses". EPA staff responded that they had modelled exposure downwind from leakage of dichlorvos sprayed within a glasshouse. The model used only allowed them to use 20 m for the exclusion zone.

- 3.12.18. Stuart Davis, from New Zealand Squash and Vegetables, spoke of the practicalities of dichlorvos use across a number of cropping sectors. For example, in brassicas, it is *"used sparingly in early crop or as a late crop clean up ... as a means of extending the whole programme and making sure that if you have a late generation of diamond back moth for instance that it's being hit with something that it hasn't had before"*.
- 3.12.19. Stuart outlined the industry programme for testing, and the progress in the search for alternatives, and he finished by asking the Committee for more time. He suggested a minimum of one year and that stretching out to five years would be consistent with the last OPCs reassessment.
- 3.12.20. Ian Turk, Manager of the Persimmon Council, spoke on behalf of the persimmon industry. They made a submission to support the continued use of dichlorvos. *"Dichlorvos ... is one of the few chemicals that are registered for persimmons. ... The loss of dichlorvos would be the removal of one of the few label chemicals we have."* Ian explained that dichlorvos is used for orchard clean up because of its short withholding period and he spoke at length about stringent phytosanitary requirements for export of persimmons; for example, *"growers exporting to Japan have very tight requirements for export. The fumigant action gets right under [the calyx] and will just kill anything that's hiding there."* He also provided detail on the lower frequency of use in persimmon orchards than that compiled in the EPA staff report.
- 3.12.21. Ian considered there is a need to give our trading partners assurances that New Zealand can provide them with the pest-free exports they want. He stated that dichlorvos provides the highest cost-benefit return ratio available for use in the sector. *"We ask the Committee to consider how the persimmon industry will be able to manage without dichlorvos"*.
- 3.12.22. The Committee heard from Nikki Johnson representing the Asparagus Council. She explained that the substance containing dichlorvos and marketed as Insectigas was no longer being supported by the registrant for the asparagus sector as it is a small sector. Withdrawal of support by the registrant had occurred since the Asparagus Council made its written submission on the reassessment application. Therefore asparagus growers can no longer use the product.
- 3.12.23. From these growers and representatives of growers, the Committee heard very specific details relating to the risks and benefits of dichlorvos use, the application methods, the relatively low application frequencies, and concerns about the lack of availability of alternatives.
- 3.12.24. EPA staff were given the opportunity to reply to comments that arose during the hearing. Matthew Allen responded and said *"There's an element of risk we haven't heard greatly represented. The levels of uncertainty give rise to the pretty stringent regime the staff have*

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proposed. We don't apologise for that but we recognise that it might create difficulties for industry. However, we still maintain that small scale use is the only exposure scenario we can support". Matthew did concede that elements of the EPA staff risk assessment were very conservative.

- 3.12.25. EPA staff added that in terms of controls and compliance measures, label instructions are a key tool in getting instructions to users. *"We do try to provide guidance material for users. There's an obligation on Approved Handlers that they should know the controls on the substance they are using. Knowing how to access that information is part of the approved handler course."*
- 3.12.26. In terms of semi-automated application, Matthew added *"we still don't have a model to assess the effect. In the absence of further information, we cannot support its further use"*.
- 3.12.27. In conclusion, the EPA staff acknowledged that there is significant benefit for horticultural and agricultural use of dichlorvos, but less benefit demonstrated for non-horticultural/agricultural purposes and for domestic use and sensitive areas. *"We don't see there is a necessity to retain approvals for those purposes"*. Furthermore, EPA staff remained *"unconvinced that large scale use can be safely managed"*.

4. Treaty of Waitangi (Te Tiriti ō Waitangi)

4.1. Introduction

- 4.1.1. Under section 8 of the Act, all persons exercising powers and functions under the Act are to take into account the principles of the Treaty of Waitangi (Tiriti ō Waitangi).
- 4.1.2. 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.
- 4.1.3. 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.”¹
- 4.1.4. The Crown’s duty of active protection is the obligation to take positive steps to ensure Māori interests are protected. Further, 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.

4.2. Response from submitters

- 4.2.1. The Committee heard from James Whetu of Ngā Kaihautū Tikanga Taiao and Dr Oliver Sutherland on behalf of the Ngāi Tahu HSNO committee.
- 4.2.2. Ngā Kaihautū Tikanga Taiao (NKTT), the statutory committee established under the Act to advise the EPA on Māori issues, prepared its own report on the reassessment application during the public submissions period. The Committee also heard an oral presentation (via teleconference) from NKTT where there was an opportunity for them to expand on their submission and answer questions.
- 4.2.3. NKTT generally supported the EPA’s reassessment of dichlorvos and their recommendations to phase out most uses. Ngā Kaihautū noted there may be additional effects of dichlorvos on Māori as tāngata whenua and in undertaking kaitiaki practices².
- 4.2.4. NKTT agreed with the general concerns regarding hauora tinana (human health) expressed in the reassessment application. For example, section 4.24 of this application which claims an unacceptable exposure level of 3 to 71 times higher than recommended operator exposure limits (even when full PPE and RPE are utilised).

¹ P. McDonald (September 1991) “Consultation with Iwi” Planning Quarterly pp8-10

² Section 2 of the Ngā Kaihautū report App202097.

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- 4.2.5. Finally, NKTT recommended that controls for any ongoing use of dichlorvos take into account effects on Māori. For example kaitiaki practices and ensuring customary food gathering practices and food gathering areas, remain unaffected by exposure to dichlorvos³.
- 4.2.6. The Ngāi Tahu HSNO committee expressed concerns over what were termed unresolved issues. These included human health, mahinga kai, rongoa, a lack of consultation, and native species testing.
- 4.2.7. Human health aspects of dichlorvos are dealt with in other sections of this report. Dr Sutherland, on behalf of the Ngāi Tahu HSNO committee, acknowledged that risks will be minimised if broad scale use of dichlorvos is prohibited as a result of this application. Ngāi Tahu recommended that assessing the risks of contaminated food needs to be picked up by a responsible government department (for example, this work is not currently performed by the Agricultural Compounds and Veterinary Medicines Group, MPI, or EPA). Dr Sutherland recommended that the EPA support native species testing based on an approach outlined in a Chinese scientific research publication⁴.
- 4.2.8. An earlier NKTT report, for APP201045, stated that *“because OPC’s are extremely toxic, the EPA has adopted a conservative approach to risk, and therefore NKTT consider it unlikely that further evaluation of native species susceptibility will dramatically alter the risk profile of OPC’s that are being reassessed”*.
- 4.2.9. The Committee acknowledged that gaps in research in the New Zealand specific context exist but considered that enough is known about the risks of dichlorvos to make an informed decision.

³ Section 24 of the Ngā Kaihautu report App 202097.

⁴ 2015, Xiaowei Jin et al. Environmental Toxicology and Chemistry DOI 10.1002/etc.2985
DO WATER QUALITY CRITERIA BASED ON NON-NATIVE SPECIES PROVIDE APPROPRIATE PROTECTION FOR
NATIVE SPECIES

5. Hazard classifications

- 5.1.1. As part of the reassessment, EPA staff reviewed the HSNO classifications for dichlorvos and formulated substances containing it. A number of changes to the classifications were proposed.
- 5.1.2. Classifications for the active ingredients were reviewed based on data from international regulators and other authorities. For the formulated substances containing the active ingredients, classifications took into account:
 - The revised classifications for the active ingredients
 - Changes in the mixture rules applied by the EPA in establishing classifications (summation, rather than additivity, is now used for mixture rules to derive ecotoxicity classifications for mixtures)
 - Any changes in the classification of the other components of the mixtures that may have occurred since the original classification was carried out.
- 5.1.3. The Committee adopted the classifications listed in Appendix A.

6. Acceptable Daily Intakes

6.1. Role of the EPA in establishing Acceptable Daily Intake values

- 6.1.1. The Acceptable Daily Intake (ADI) is a value used to assess the human health significance of estimated intakes of pesticides from food. The ADI is derived from toxicological and/or epidemiological findings and is set to represent the oral intake of a pesticide that a human can consume daily for a lifetime without adverse effects. ADIs are important because MPI's Agricultural Compounds and Veterinary Medicines (ACVM) Group use them to assess dietary pesticide intakes and to establish Maximum Residue Levels (MRLs) for pesticides on food crops.
- 6.1.2. The EPA has the legislative mandate under the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 to set exposure standards for hazardous substances. This includes setting values for the ACVM Group to use in assessing the human health significance of food residues for pesticide and veterinary medicine active ingredients.
- 6.1.3. The EPA's role under the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 is to define the following values:
- Acceptable Daily Exposure (ADE) values – a daily exposure to a substance that is not considered to represent a health hazard over a lifetime of exposure
 - Potential Daily Exposure (PDE) values – established to represent various sources of exposure. The EPA has generally set three PDE values:
 - PDE_{food}, usually 70% of the ADE
 - PDE_{drinking water}, usually 20% of the ADE
 - PDE_{other}, usually 10% of the ADE.
- 6.1.4. After setting the values, the EPA advises the ACVM Group of the ADE and PDEs, with particular attention to the PDE_{food} as this value is used by ACVM as the ADI.

6.2. Selection of ADIs under the present reassessment

- 6.2.1. Market Access Solutionz asked for clarification regarding whether an ADI value has been set for dichlorvos and on what basis. An ADI for dichlorvos of **0.001 mg/kg bw/day** was established during the organophosphate and carbamate (OPC) plant protection insecticide reassessment (APP201045⁵). This is also the ADI established by the APVMA and is based on the same 28-day study in human volunteers as that used to derive the Acceptable Operator Exposure Level (AOEL: Rider, 1967; APVMA, 2008). The ADI is based on the No Observed Effect Level (NOEL) of 0.014 mg/kg bw/day for plasma cholinesterase (ChE)

⁵ http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP201045_APP201045_Decision_FINAL.pdf

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inhibition, and then incorporating a 10- fold uncertainty factor to account for variation in susceptibility among members of the human population.

- 6.2.2. The Committee noted that the ACVM Group is engaging with the agricultural industry and registrants about the process for refining or deleting label claims. We endorse this approach and expect this dialogue to continue to ensure that any resultant MRL, label claims and possible restrictions on off label use does not lead to a perverse outcome that potentially undermines this decision.

7. Current management regime

- 7.1.1. The current controls applying to dichlorvos and its formulations were prescribed as part of their approval under the Act. Other requirements that must be complied with are set out in the ACVM Act 1997, Resource Management Act 1991 (RMA), the Health and Safety in Employment Act 1992, Biosecurity Act 1993 and the Civil Aviation Act 1990.
- 7.1.2. The current controls comprise the default controls assigned based on their hazardous properties, with variations and additions which were applied either at the time of transfer from the Pesticides Act 1979 to the framework of the Act, or when an approval was granted following the time of transfer under Part 5 of the Act.
- 7.1.3. The current controls were used as a reference point in the evaluation and risk assessment. The risk assessment was carried out with the assumption that the current controls, together with some additional controls, are in place
- 7.1.4. The primary users of dichlorvos and its formulations in New Zealand are the horticultural/agricultural sectors. Many commercial growers follow formal good practice standards which ensure the safe and efficient use of agrichemicals. The main standards followed are those of Good Agricultural Practice (GAP) and New Zealand Standard NZS8409:2004.
- 7.1.5. GLOBALGAP is an internationally recognised food safety tool describing best practice for safe, effective chemical use. There is a local version, called New Zealand GAP. For markets where retailers accept systems equivalent to GLOBALGAP, additional features are incorporated into the New Zealand GAP used domestically, and this practice is recognised as equivalent to GLOBALGAP. Under GAP, the user should achieve the desired pest control without excessive use of chemicals, leaving a residue which is the smallest amount practicable. While this may achieve some risk reduction in relation to food residues, it is unlikely to reduce the human health and environmental risks identified in the application.
- 7.1.6. NZS8409:2004 is the New Zealand Standard for the Management of Agrichemicals. It provides guidance on the safe, responsible and effective management of agrichemicals and is an approved code of practice under HSNO. As a code of practice it has mandatory and non-mandatory elements embodied within it. Adherence to the mandatory requirements means that HSNO obligations for the entire life cycle of an agrichemical are met. Adopting the non-mandatory best practice measures will also ensure that HSNO obligations are met.
- 7.1.7. In addition many users of agrichemicals are Growsafe trained and hold appropriate certificates. A Growsafe certificate is issued at the completion of a Growsafe course, and demonstrates that agrichemical users understand their obligations and best practice for the use of agrichemical products (within the scope of their certification).

8. Assessment of benefits

8.1. Summary

- 8.1.1. The Committee's view, set out in more detail below, is that, the benefits of dichlorvos and its formulations are considerable both at a national and regional level.

8.2. Introduction

- 8.2.1. The Committee reviewed the EPA staff assessment of the potential benefits. In addition, the Committee heard from a number of submitters, particularly those from the horticultural sector as to the benefits that dichlorvos has in managing pests, particularly in critical situations. Further, the Committee considered the NZIER cost benefit analysis which outlined the economic benefits from the ongoing use of dichlorvos and its formulations. The industry submitters also provided additional comment on the economic benefits of dichlorvos use.

8.3. Market economy benefits

- 8.3.1. The Committee heard that the most significant benefit relates to support of the export and domestic agricultural industry and the associated positive effects on the market economy.
- 8.3.2. The submissions identified a number of key benefits, namely its volatility and the contribution of this property to the treatment of a broad range of insects, and a short withholding period.
- 8.3.3. The Committee heard that some benefits can be delivered to varying degrees by other substances. However, the overwhelming information received was that there are few alternatives with the same short withholding period. For some pests, the Committee heard that there are no alternative substances that can adequately replace dichlorvos. The generic benefits include:
- **Efficacy:** Reliability and effectiveness of dichlorvos were identified as important benefits
 - **Broad spectrum:** Control of a wide variety of pests means that fewer applications achieve the same level of control as more targeted substances
 - **Short pre-harvest interval:** The short period between application and harvest whereby crops can be harvested for human and animal consumption a day after treatment is particularly beneficial for controlling some insect pests
 - **Short re-entry periods:** Workers and livestock can quickly return to a sprayed area, maximising productivity
 - **Maximum Residue Limits:** Meeting MRLs is important to ensure that international trading partners do not reject the produce. For some crops, specific MRLs are set. Use of other substances without MRLs may not be permitted on crops exported to some overseas markets, or may require growers to meet default MRLs which can be difficult.

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- **Resistance Management:** Dichlorvos is considered an important tool for resistance management
- **Biosecurity:** Dichlorvos is considered an important tool for biosecurity, which is crucial to meet the phytosanitary requirements of our international trading partners.

8.3.4. The information provided by submitters was that these combined generic benefits allow good quality crops to be produced in sufficient quantities to meet demand and ensure New Zealand growers remain a major contributor to local and national economies.

8.3.5. The Committee focused its assessment of benefits on the two main areas of use: indoor and outdoor horticulture and agriculture. An additional consideration was the use for biosecurity purposes. The Committee considered that the risks associated with the current biosecurity uses can be mitigated to negligible levels through application of the new controls, and therefore did not assess the benefits of biosecurity uses in detail.

8.4. Benefits from non-horticultural / agricultural use

8.4.1. The Committee noted that dichlorvos and its formulations are not considered critical by non-horticultural/agricultural users.

8.4.2. The Committee further noted that no submissions were made during the hearing process which highlighted any previously unknown benefits from this use.

8.4.3. The Committee therefore agreed with the EPA staff assessment that the benefits from the use of dichlorvos in non-horticultural/agricultural settings are considerably outweighed by the risks associated with such use.

8.5. Benefits from indoor / outdoor horticultural / agricultural use

8.5.1. The Committee recognised the contribution to the national economy provided by the horticulture/agricultural sector as a whole. The Committee also considered that some specific crops, although comparatively small in isolation, provide substantial regional benefits.

8.5.2. Industry representatives expressed concern at the phase out period suggested by EPA staff and stated that there would be insufficient time to develop alternatives. Although development work by international companies is currently underway, the industry is not aware of alternatives that could undergo field trials in the next few years.

8.5.3. The Committee heard about the importance of this substance for the control of the recent devastating tomato potato psyllid (TPP) in tomatoes, for green vegetable bug on sweetcorn and maize, and for control of storage weevils in grain silos.

8.5.4. Control of TPP and green vegetable bug is considered vital for the ongoing existence of the affected industries, all of which provide benefits for regional economies and are collectively nationally beneficial.

8.6. Benefits to biosecurity

- 8.6.1. The Committee considered that two formulations covered under this reassessment (HSR000211 Nuvos; and HSR000213 Divap), have benefits to the biosecurity values of New Zealand.

8.7. Human health benefits

- 8.7.1. The Committee considered that there are social health benefits from dichlorvos resulting from employment in horticulture/agriculture where dichlorvos use is critical for crops like persimmons and tomatoes, and from lower food prices if crop yields are not reduced due to lack of pest control.

8.8. Benefits to Māori

- 8.8.1. The Committee noted that no submissions were received from Māori identifying any specific benefits to Māori arising from the continued use of dichlorvos. In fact, the Committee noted that the submissions received from Maori are generally opposed to the continued use of dichlorvos and its formulations.
- 8.8.2. The Committee considered that, generally, Māori will likely benefit from the continued use of dichlorvos through involvement in the primary sector. Māori participate in the horticulture and agriculture industries at various levels (including as producers and workers), such that the general benefits to those industries from the continued use of dichlorvos will apply to Māori participating in those industries. However, the Committee was also mindful of the points well made by NKTT regarding the relatively high incidence of Māori working in those industries in roles that are susceptible to exposure to dichlorvos and the potential effects of the use of the substance on traditional food sources.
- 8.8.3. The Committee noted that the level of benefit in this area must be weighed against the significant risks that have been identified.

8.9. Benefits to society and communities

- 8.9.1. EPA staff identified a positive effect on society and communities in terms of reducing anxiety associated with expectations of future capability to counter pest problems. Users across the industry sectors have expressed their concerns that loss of dichlorvos would have negative effects on themselves, their families and local communities.
- 8.9.2. The EPA staff also noted that there may be a social benefit from the continued use of dichlorvos in that it may be cheaper than alternative substances, when those alternatives are developed.
- 8.9.3. The Committee considered these positive effects result in tangible benefits to society and communities.

9. Assessment of adverse effects

9.1. Adverse effects on human health

- 9.1.1. Dichlorvos is known to affect the nervous system through the inhibition of the enzyme acetylcholinesterase. Acetylcholinesterase breaks down acetylcholine, a chemical which transmits nerve signals. Inhibition of acetylcholinesterase results in accumulation of acetylcholine, leading to overstimulation of the nervous system.
- 9.1.2. Even minor effects on enzyme levels are potentially of concern as it can take several months for normal enzyme function to be restored. There is also a risk of cumulative effects, as another exposure during a time of depressed cholinesterase enzyme levels can further reduce these levels. This increases the probability that an individual may experience adverse health effects.

Acute poisoning

- 9.1.3. The acute effects of exposure to high levels of dichlorvos are well established from animal studies and numerous human poisoning incidents.
- 9.1.4. Short term exposure can result in symptoms including increased sweating and salivation, dizziness, fatigue, runny nose or eyes, nausea, intestinal discomfort, confusion and changes in heart rate. At high levels of exposure more severe effects such as paralysis, seizures, loss of consciousness and death may occur.
- 9.1.5. In addition to the immediate effects, there are a number of possible neurological complications that can develop in the subsequent days-weeks following initial recovery: Intermediate syndrome (IMS) and OP-Induced Delayed Polyneuropathy (OPIDP).
- 9.1.6. The Committee noted that there is a paucity of data on dichlorvos poisoning incidents in New Zealand. The extent of acute poisoning relating to organophosphate (let alone dichlorvos) plant protection use is unknown. However, the Committee was not convinced that the relative lack of reported cases is representative of the level of acute poisoning in New Zealand. The symptoms of dichlorvos poisoning are non-specific and the time of onset varies depending on the route and severity of exposure. The Committee therefore considered under-recognition and under-reporting likely.
- 9.1.7. The former Department of Labour has produced guidelines for the monitoring of blood acetylcholinesterase levels in workers exposed to OPs⁶. The level of acetylcholinesterase in blood acts as a marker for the level of the enzyme in nervous tissue. Following baseline test(s) before organophosphate exposure begins to establish a worker's normal level, periodic testing detects whether a regular organophosphate user's enzyme levels have decreased to such a level that further exposure could result in symptoms. If the decrease

⁶ Occupational Health Service (2000). A Guideline to Promote Best Practice with Organophosphates. Wellington: Department of Labour.

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from baseline level is 40% or greater workers should be suspended from work until the level recovers.

- 9.1.8. While the Committee heard about some monitoring programmes, there is variable knowledge and understanding among users about how to carry out monitoring effectively in order to protect their health. Further work is needed to enhance the effectiveness of biological monitoring, and the Committee recommended that EPA staff draw this to the attention of WorkSafe.

Chronic health effects

- 9.1.9. As well as acute toxicity, concerns have been raised over the potential for longer term adverse health effects. This includes the potential for chronic health effects following acute poisoning and for effects as a result of chronic exposure to low levels that do not cause the clinical signs or symptoms of poisoning.
- 9.1.10. Animal and human epidemiological studies have reported associations between acute and/or chronic exposure and a number of adverse effects. Examples of the type of effects that have been raised as concerns are:
- Neuropsychological effects e.g. on attention, perception and memory
 - Effects on motor function and muscle coordination
 - Effects on the development of the nervous system following pre-natal or childhood exposure
 - Psychiatric illness e.g. anxiety and depression
 - Parkinson's disease
 - Increased risk of cancer
 - Increased risk of obesity and diabetes.

9.2. Adverse effects on the environment

- 9.2.1. Dichlorvos is harmful to living organisms in the environment, not only to target insects. It is very toxic to some aquatic life and to terrestrial invertebrates (e.g. bees), and in general to birds.

9.3. Risk Assessment

- 9.3.1. EPA staff undertook a human health and environmental risk assessment for dichlorvos and its formulations in use in New Zealand.
- 9.3.2. The risks of adverse effects on human health were assessed by comparing predicted exposures of the substances to operators, workers re-entering a recently sprayed area and bystanders, with the maximum levels of exposure that are generally not expected to result in

harmful effects. The risks of adverse effects on the environment were assessed by comparing predicted exposures of the substances to wildlife against concentrations known to cause a particular level of effect.

- 9.3.3. The data relating to the toxicological and ecotoxicological effects are based on animal or human studies. Where possible, the toxicity and ecotoxicity data specific to the substances evaluated are those used by other international regulators. In some instances key information relevant to the risk assessment, such as higher tier operator or re-entry worker exposure monitoring studies or dermal absorption data were not available. In these instances, EPA staff followed international practice and used reasonable worst case scenarios or default values, or did not calculate the risks.
- 9.3.4. Exposure was assessed using application rates and methods provided by stakeholder feedback, as well as the application rates and methods listed on product labels.
- 9.3.5. The risk assessment assumed that the default controls triggered by the hazard classifications were in place, as well as the following additional controls: buffer zones, use of PPE including respiratory protective equipment (RPE), label warnings of the effects on bees, and re-entry intervals (REI).
- 9.3.6. To allow a comparison between the benefits and the risks associated with the application of dichlorvos and its formulations, qualitative descriptors were used which assign the level of risk into broad categories of negligible, low, medium or high. In line with the EPA's Methodology, these descriptors took into account the likelihood and magnitude of an adverse effect. The Committee considered that even low risks are of concern.
- 9.3.7. Full details on the risk assessment approach and results can be found in the application and the EPA staff update report.

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

- 9.4.1. Ngāi Tahu in particular expressed clear concerns regarding the environmental dangers and acute risks to aquatic invertebrates, birds and bees for all outdoor agricultural uses. Ngāi Tahu supported the final conclusion of the application, that "*no amount of refinement of the risk assessment will be able to sufficiently reduce the risks identified in outdoor agricultural uses of dichlorvos*".

9.5. Adverse effects on society and communities

- 9.5.1. In addition to human health effects or discrete incidents of harm to the environment, the Committee considered that there is a broader adverse effect associated with the use of dichlorvos which results from general social concern and anxiety associated with its use.

9.6. Withdrawal of products from the market

- 9.6.1. The Committee decided to revoke the approvals for two formulations that contain dichlorvos (Flammable aerosol containing 3.1 g/L dichlorvos and 8.7 g/L propoxur. Trade name: BV2

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Surface Insecticide: HSR000207, and Ready-to-use liquid containing 4.4 g/L dichlorvos and 9.6 g/L propoxur. Trade name: BV2 Surface Insecticide Bulk: HSR000209).

- 9.6.2. They are both used in domestic settings or a setting where there are typically bystanders, and with no guarantee that appropriate PPE will be worn, so the risks are significant and there is a limited ability to mitigate them. The Committee considered the staff report on these formulations to be accurate and noted that the incidents of harm reported to WorkSafe relate to these formulations and usages in buildings or parts of buildings which had been sprayed and in which bystanders had not been informed.
- 9.6.3. The Committee also noted that these formulations were available for public use to treat fleas in their homes and considered this an unacceptable use.
- 9.6.4. The Committee considered the consequences of these substances being unavailable. Such use is high-risk and is not essential, as less hazardous alternatives are available. Therefore the Committee decided to withdraw approval for these products.
- 9.6.5. The Committee is aware of community concerns about the health risks related to use of agrichemicals. In general it is bystanders who are worried about unintentional exposure of themselves, their children and pets. This is supported by regional council records of complaints made to them about spray drift from agrichemical application. The risk to bystanders has been modelled in the EPA staff assessment.

10. International obligations

- 10.1.1. To achieve the purpose of HSNO, the EPA must consider the impacts of the application on New Zealand's international obligations.
- 10.1.2. The EPA staff have identified that all OPCs must meet the World Health Organization/Food and Agriculture Organisation Joint Meeting on Pesticide Specifications (JMPS) standards. Dichlorvos is covered under this obligation.

11. Revised management regime

11.1. Introduction

- 11.1.1. Section 7 of this decision provides an overview of the current management regime for dichlorvos and its formulations. This section outlines how the Committee considers a revised management regime will operate.
- 11.1.2. Nikki Johnson (MAS) commented at the hearing that *"We recognise that there are issues here and we need to find alternatives. ... Industry needs a phase out time that allows us to adopt alternatives; 12 months is impractical. There are practicalities involved with removing a product within 12 months. The impact will be severe and is inconsistent with the previous OPC reassessment. We request the time to find alternatives to replace dichlorvos"*. She added that for persimmons *"we don't know what we might replace it with and in the meantime....will lose export markets"*. She considered that five years would be an absolute minimum and that 10 years would be a logical answer for finding developing and registering an alternative.
- 11.1.3. Ben Smith spoke to the phase-in times proposed by EPA staff: *"we're going to need some time to make this work. I've put forward three to five years if we go for fully auto if that's the way we decide to go"*. He added *"Whatever the outcome of today is, please make sure it's on the label"*, as he explained that labels are how growers and operators understand the operational requirements of the product they are using.
- 11.1.4. EPA staff proposed a phase-in of controls over a 12 month period with no phase-out of the product absolutely but an effective phase-out on a number of use patterns immediately on implementation of controls.
- 11.1.5. The Committee considered both these perspectives and decided that a phase-in period of five years appropriately balances these concerns.
- 11.1.6. Implementation of new additional controls will be staged over five years from the date of this decision, to allow sufficient time for compliance with the revised controls to be arranged. In determining that five year phase-in period for the new, additional controls, the Committee considered that interim measures should be phased in two years from the date of this decision. These interim measures will improve the current risk management of dichlorvos and its formulations.
- 11.1.7. Some controls are to commence six months from the date of this decision. These relate to current use patterns that the Committee considered unacceptable, for example, aerial application is to be phased out within six months of this decision.
- 11.1.8. The full list of controls (default and additional) applied to each substance is provided in the accompanying Controls Annex.

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- 11.1.9. Where new controls are imposed on a substance, the revised controls package comes into effect after a transition period in order to allow for compliance with the revised controls to be arranged. In each substance approval, the controls imposed as a result of this reassessment will be identified with an implementation date.

11.2. Managing risk through permission applications

- 11.2.1. The risks to bystanders are considered to be significant for large-scale indoor use of dichlorvos when the Enclosed Space is located within 20 m of a Sensitive Area. Additional risk mitigation measures must be implemented to address this.
- 11.2.2. The Committee noted that requiring users to obtain permission under section 95A of the Act will help to ensure that relevant site-specific considerations that are unable to be factored into this Decision can be assessed. This may include details around the circumstances of the dichlorvos use and the specific measures that will be implemented by the person(s) in charge to ensure that bystanders are informed and protected.
- 11.2.3. The Committee considered that there are a number of critical pieces of information that will describe the circumstances of dichlorvos use where permission is required. This information needs to be assessed in order to determine whether the local effects to bystanders associated with dichlorvos use can be managed. These pieces of information are identified in the Table 1.

Table 1: Minimum information requirements for permission application

Information requirement	Purpose of providing information	Example of how to meet obligation
<p>Purpose of dichlorvos use</p> <ul style="list-style-type: none"> - Why dichlorvos use is needed - Target pests - Consideration of alternatives 	<p>This information is required to detail why dichlorvos is required to be used for a particular operation</p> <p>It is proposed that this involves discussion of consideration of alternative substances. This will be used to verify that use of dichlorvos is appropriate, and that lower risk alternatives have been considered</p>	<p>Complete relevant sections of permission application, with as much detail as possible to allow an informed decision</p>
<p>Details of site</p> <ul style="list-style-type: none"> - physical address - overview map, with scale, of location of property - detailed map, with scale, including <ul style="list-style-type: none"> o facility within property o Sensitive Areas within Exclusion and Notification Zones 	<p>This information is required to provide unequivocal identification of the location of site, and precise location of specific facilities within a site</p> <p>This information is critical to determine the affected locations, and to demonstrate an appreciation of critical controls, such as the use of Exclusion and Notification Zones</p> <p>Additionally, information on the type of Sensitive Area is important. For example,</p>	<p>Complete relevant sections of permission application form, with as much detail as possible to allow an informed decision, plus:</p> <ul style="list-style-type: none"> - provide an overview map (of site/property, with appropriate annotation. This could be provided in electronic format (such as “.kml”). - provide a detailed

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Information requirement	Purpose of providing information	Example of how to meet obligation
<ul style="list-style-type: none"> ○ details on the identified Sensitive Areas (e.g. nature, type of occupancy) ○ identification of Exclusion and Notification Zones - detailed diagram of facility, including <ul style="list-style-type: none"> ○ details of types of property/operation ○ location of ventilation ports ○ identification of Exclusion and Notification Zones 	<p>if the Sensitive Area is a site that is not occupied at the weekends or during school holidays, then that may affect the conditions that are imposed</p>	<p>map/image (with scale) of the facility / facilities, in relation to all relevant neighbouring properties, plus relevant annotations to identify the specified details.</p> <p>Maps and diagrams should be sufficiently detailed to allow the specified requirements to be clearly identified</p>
<p>Contact details</p> <ul style="list-style-type: none"> - Person(s) in Charge of: <ul style="list-style-type: none"> ○ Application Area / Enclosed Space ○ Application of the substance - Approved Handler details 	<p>Details of the person in charge and approved handlers will allow on-going correspondence with key operational personnel involved in applications of dichlorvos</p>	<p>Complete relevant sections of permission application, with standard contact detail requirements:</p> <ul style="list-style-type: none"> - contact address - contact phone number - email address
<p>Operational details</p> <ul style="list-style-type: none"> - how dichlorvos is to be applied - how much dichlorvos is to be applied - how often dichlorvos is to be applied - on-going or one-off use - measures in place to prevent bystander exposures 	<p>These details provide context regarding the nature of dichlorvos use and application, and also frequency of intended use</p> <p>These details will impact on the conditions imposed in any resulting permission approval. For example, the conditions for infrequent or one-off use may not be appropriate to manage the risks associated with frequent, routine use</p>	<p>Complete relevant sections of permission application with as much detail as possible to allow an informed decision</p>
<p>Bystander management plan</p> <ul style="list-style-type: none"> - notification of neighbours - measures implemented to restrict access of bystanders into Exclusion Zone 	<p>The bystander management plan and notification plan would be crucial parts of the permission application, which will provide details of measures to be implemented to inform and protect bystanders</p>	<p>The applicant will be expected to produce a Bystander Management Plan and a Notification plan, appropriate to their site and operation. These documents should be submitted as part of the permission application</p>
<p>Notification plan</p> <ul style="list-style-type: none"> - neighbours - regular visitors to site - local medical officer of health 	<p>These requirements should include:</p> <ul style="list-style-type: none"> - details of who is required to be notified, and their corresponding address/property location - method of notification 	<p>These documents may be referenced in any conditions that are attached to a resultant permission approval, and would therefore be required to be</p>

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Information requirement	Purpose of providing information	Example of how to meet obligation
	<ul style="list-style-type: none"> - measures to protect bystanders in Sensitive Areas within the Exclusion Zone - measures to protect visitors to site <p>Detailed procedures for bystander protection will be expected to be provided, which would include details of any air quality monitoring that should be undertaken to monitor dichlorvos levels at the property boundary</p>	<p>complied with</p>
<p>Record keeping and reporting</p> <ul style="list-style-type: none"> - Specific measures that would be recorded (above and beyond control T3) - Reports of adverse effects on bystanders (actual or perceived) to <ul style="list-style-type: none"> o Medical Officer of Health o WorkSafe o EPA 	<p>These requirements would be in addition to the requirements specified in controls T3 and E5, including identification of Sensitive Areas and affected people</p> <p>In the event of any reports of adverse effects, these should be provided to relevant authorities to decide whether further action or investigation is warranted</p>	<p>The applicant should outline in the permission application how adverse effects (perceived or actual) can be reported, and measures to be implemented to monitor whether adverse effects are arising from their operation</p> <p>Records should be kept, detailing who was notified, to meet the requirements of a permission. This is in line with the 'standard' record keeping requirements for notification</p>

11.2.4. The Committee considered that permission would only be granted based on the specific circumstances outlined in the permission application, and therefore that any resulting permission approval should be time-limited. This is consistent with the approach for s95A permissions that have previously been granted for other hazardous substances. Should particular circumstances around the dichlorvos use change significantly (such as use quantities, frequencies, change to Sensitive Areas), then it may be necessary to review a permission granted, in light of those changes.

11.2.5. The Committee considered that the requirement to obtain permission for certain circumstances of use of dichlorvos is restricted to sites where a Sensitive Area is within the Exclusion Zone, which reflects the level of concern for bystander safety in close proximity to an operation. The Committee considered that, where there is a viable alternative substance that could be used in place of dichlorvos, and then the requirement to obtain permission prior to dichlorvos use will ensure that users give appropriate consideration to alternative, lower risk substances before undertaking dichlorvos applications. Additionally, the information requirements to apply for permission are detailed and will be comprehensively reviewed by the EPA to ensure that any risks to bystanders are adequately managed.

- 11.2.6. The Committee noted that permission requirements will be introduced when the additional controls are implemented, which will provide affected operations sufficient time to apply for a permission.

12. Overall evaluation of effects

12.1. Introduction

- 12.1.1. The overall evaluation of risks, costs and benefits was carried out having regard to the tests in clause 27 of the Methodology and section 29 of the Act.
- 12.1.2. 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.

12.2. Greenhouses and grain silos

- 12.2.1. The Committee identified substantial benefits from the use of dichlorvos in greenhouses and grain silos.
- 12.2.2. In addition to the generic benefits, the Committee also took note of the specific benefits provided by dichlorvos, in particular the critical need for the control of whitefly, for which there is a lack of effective alternative control options. The Committee also noted the specific use of dichlorvos in control of grain weevils.
- 12.2.3. The Committee also identified risks for human health and the environment from the use of dichlorvos.
- 12.2.4. The Committee considered that in general the economic benefits provided by use of dichlorvos in glasshouses and silos (indoor use) outweighed the adverse effects of these substances.

12.3. Horticulture

- 12.3.1. The Committee considered the outdoor horticulture sector, noting that while some specific crops may be relatively small industries, in combination they are valuable to the national economy. They have regional benefits through provision of employment and they contribute to the diversity of the New Zealand horticulture industry and domestic food supply.
- 12.3.2. The Committee recognised that dichlorvos is needed in the outdoor horticulture sector to maintain productivity, and therefore considered the level of benefit from use of these substances to be high. As well as the generic benefits, the Committee noted that dichlorvos is critical for persimmons due to its effectiveness in penetrating under the calyx of the fruit immediately prior to export, thus achieving the high phytosanitary requirements of our export trade partners.

12.4. Biosecurity

- 12.4.1. The Committee noted that dichlorvos is a particularly important tool for use by MPI for biosecurity. The Committee considered that the human health and environmental risks associated with the use of dichlorvos are outweighed by the benefit of providing a tool in the biosecurity toolbox.

12.5. Summary and conclusions

- 12.5.1. The Committee noted that use of dichlorvos and its formulations is associated with a number of non-negligible adverse effects, and therefore the decision was made based on clause 27 of the Methodology.
- 12.5.2. Given the benefits of dichlorvos through its value to the New Zealand primary production industry, and for biosecurity purposes, the Committee considered that, with the implementation of the revised management regime requiring additional controls, the adverse effects can be managed to a level where the positive effects outweigh the risks.
- 12.5.3. The Committee noted that there is the potential for the specific benefits currently possessed by these dichlorvos products to decline with the development of alternatives. Therefore, once alternatives are developed and proven to be valid then it is likely that the risks associated with these dichlorvos products would outweigh their benefits.
- 12.5.4. Given the high risks associated with the use of dichlorvos, the Committee considered that long term use is undesirable. Research by manufacturers and users into safer alternatives is needed in order to enable dichlorvos and its formulations to be replaced.

13. Decision

- 13.1.1. Pursuant to sections 63 and 29 of the Act, the Committee has considered this application to reassess dichlorvos and its formulations used as plant protection insecticides.
- 13.1.2. The Committee considered that the risks have been overestimated and the benefits underestimated as a result of conservatism in the EPA staff modelling and advice. With the additional controls, including withdrawal of some products and removal of some uses, no aerial spraying, use of buffer and exclusion zones, requirements for permission etc., the Committee considered that the risks are reduced to a level where they are outweighed by the benefits.
- 13.1.3. The Committee acknowledged that dichlorvos is hazardous, but at present, the benefits outweigh the risks as there are no alternatives. The Committee considered this will eventually change and that dichlorvos will be used less and less once true alternatives are found.
- 13.1.4. The Committee considered there is a current need for indoor use (particularly glasshouses), but would like to see this move to automated application methods so as to reduce operator exposure.
- 13.1.5. The Committee also took into account the fact that dichlorvos is being phased out by some of our export markets. If New Zealand continues to use it, it may result in a reduction of access to certain markets.
- 13.1.6. Based on consideration and analysis of the information provided, and in accordance with the Act and the Methodology, and taking into account the application of the default controls and the varied and additional controls, the Committee was satisfied, for the reasons set out in this decision, that the positive effects (benefits) associated with the use of dichlorvos and its formulations outweigh the adverse effects (risks and costs) in all but two approvals.
- 13.1.7. The application for importation and manufacture of dichlorvos and its formulations where the positive effects outweigh the adverse effects is approved.
- 13.1.8. There are two formulations included in the reassessment application for which the adverse effects outweigh the positive effects. For these substances, the application for import or manufacture of these substances is declined, and the Committee issues a direction under s66 of the Act, restricting use of these substances and imposing controls on the collection and disposal of these substances. These controls are attached to this decision as Appendix C. These substances must be disposed of by 15 March 2016.
- 13.1.9. The substances have the hazard classifications set out in Appendix A.

13.1.10. The full list of controls for each substance is listed in an Annex accompanying this decision.



Kerry Laing	
Chair, Decision Making Committee Environmental Protection Authority	Date: 15 September 2015

13.2. Addendum

13.2.1. The Committee is aware that a package of information on the use of dichlorvos, and responsibilities relating to dichlorvos use and management of bystander exposure, will be required to facilitate implementation of the new controls. The Committee recommended that this be developed to facilitate implementation of the new controls.

Appendix A: Proposed changes to the classification of dichlorvos

Table 2. Summary of the revised HSNO classifications for dichlorvos (CAS No. 62-73-7)

Hazard class/subclass	Classification
Class 1 Explosiveness	No
Class 2, 3, & 4 Flammability	No
Class 5 Oxidisers/organic peroxides	No
Subclass 8.1 Metal corrosive	No
6.1 Acute toxicity (oral)	6.1B (LD ₅₀ = 46.4 mg/kg bw [new key study])
6.1 Acute toxicity (dermal)	6.1B (LD ₅₀ = 75 mg/kg bw [new key study])
6.1 Acute toxicity (inhalation)	6.1B (LC ₅₀ = 0.23 mg/L [aerosol]) [new key study]
6.3/8.2 Skin irritant/corrosive	6.3B
6.4/8.3 Eye irritant/corrosive	6.4A
6.5A Respiratory sensitiser	ND
6.5B Contact sensitiser	6.5B
6.6 Mutagenicity	6.6B
6.7 Carcinogenicity	6.7B
6.8 Reproductive/developmental toxicity	No
6.9 Target organ systemic toxicity (oral: single, repeat)	6.9A
6.9 Target organ systemic toxicity (dermal: repeat)	6.9B
6.9 Target organ systemic toxicity (dermal: single)	ND
6.9 Target organ systemic toxicity (inhalation: single, repeat)	6.9A
9.1 Aquatic ecotoxicity	9.1A
9.1 Soil ecotoxicity	9.2D
9.1 Terrestrial vertebrate ecotoxicity	9.3A
9.1 Terrestrial invertebrate ecotoxicity	9.4A

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ND – no data to support classification or available data is of poor quality (according to Klimisch⁷ criteria); No – there are data available for the relevant endpoint and the classification does not trigger.

Substances containing dichlorvos

The revised classification of HSR000212, HSR000211 and HSR000213, and limits relating to the purity and impurity levels for the active ingredients used in these substances, are listed below, in Table 3.

The limits for dichlorvos impurities are based on the Joint FAO/WHO Meeting on Pesticide Specifications (JMPS) specification for dichlorvos, plus information received from the manufacturers. The proposed limits for the impurity methyl chloride are lower for HSR000213 than for the other two approvals: this is based on information received regarding the purity of different sources of dichlorvos, and because if methyl chloride were present at a higher concentration in this substance it would trigger an additional hazard classification that does not currently apply.

No information was received regarding the composition of the other two substances (HSR000207 and HSR000209) and these approvals have been revoked. No further action is required.

⁷ The EPA has adopted the Klimisch et al (1997) data reliability scoring system for evaluating data used in the hazard classification and risk assessment of chemicals.

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Table 3. Summary of the revised HSNO classifications for dichlorvos-containing formulations (bold text denoted classifications that have been amended based on composition and impurity information submitted following the application)

Substance name	Approval number	Final classification	Dichlorvos impurity limits
Aerosol containing 50 g/kg dichlorvos Trade name: Insectigas	HSR000212	6.1B (Dermal), 6.1C (Inhalation), 6.3B, 6.4A, 6.5B, 6.6B, 6.7B, 6.9B (Oral), 6.9B (Dermal), 6.9B (Inhalation), 9.1A, 9.3A, 9.4A	Chloral 5 g/kg max Water 0.5 g/kg max Methyl chloride: 5 g/kg max Trimethylphosphate: 4 g/kg max
Emulsifiable concentrate containing 1000 g/L dichlorvos Trade name: Nuvos	HSR000211	6.1C (Oral), 6.1B (Dermal), 6.1B (Inhalation), 6.3B, 6.4A, 6.5B, 6.6A , 6.7B, 6.8A, 6.9A (Oral), 6.9B (Dermal), 6.9A (Inhalation), 9.1A, 9.2D, 9.3A, 9.4A	Chloral 5 g/kg max Water 0.5 g/kg max Methyl chloride: 5 g/kg max Trimethylphosphate: 4 g/kg max
Emulsifiable concentrate containing 1140 g/L dichlorvos Trade name: Divap	HSR000213	6.1C (Oral), 6.1B (Dermal), 6.1B (Inhalation), 6.3B, 6.4A, 6.5B, 6.6A , 6.7B, 6.9A (Oral), 6.9B (Dermal), 6.9A (Inhalation), 9.1A, 9.2D, 9.3A, 9.4A	Chloral 5 g/kg max Water 0.5 g/kg max Methyl chloride: 1 g/kg max Trimethylphosphate: 4 g/kg max
Flammable aerosol containing 3.1 g/L dichlorvos and 8.7 g/L propoxur Trade name: BV2 Surface Insecticide	HSR000207	2.1.2A, 6.3B, 6.4A, 6.5B, 6.7B, 6.9B (Oral), 6.9B (Inhalation), 9.1A, 9.4C	No information received
Ready-to-use liquid containing 4.4 g/L dichlorvos and 9.6 g/L propoxur Trade name: BV2 Surface Insecticide Bulk	HSR000209	6.1D (Oral), 6.3B, 6.4A, 6.5B, 6.7B, 6.9B (Oral), 6.9B (Inhalation), 9.1A, 9.3B, 9.4C	No information received

Appendix B: Decision path for the reassessment of dichlorvos and its formulations

Context

This decision path describes the decision-making process for the application to import or manufacture dichlorvos and its formulations. This application is made under section 63 (Reassessment) of the HSNO Act, and determined under section 29 of the Act.

Introduction

The purpose of the decision path is to provide the HSNO decision maker⁸ with guidance so that all relevant matters in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the HSNO decision maker may decide to make on individual aspects of an application.

In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the Methodology.

The decision path has two parts –

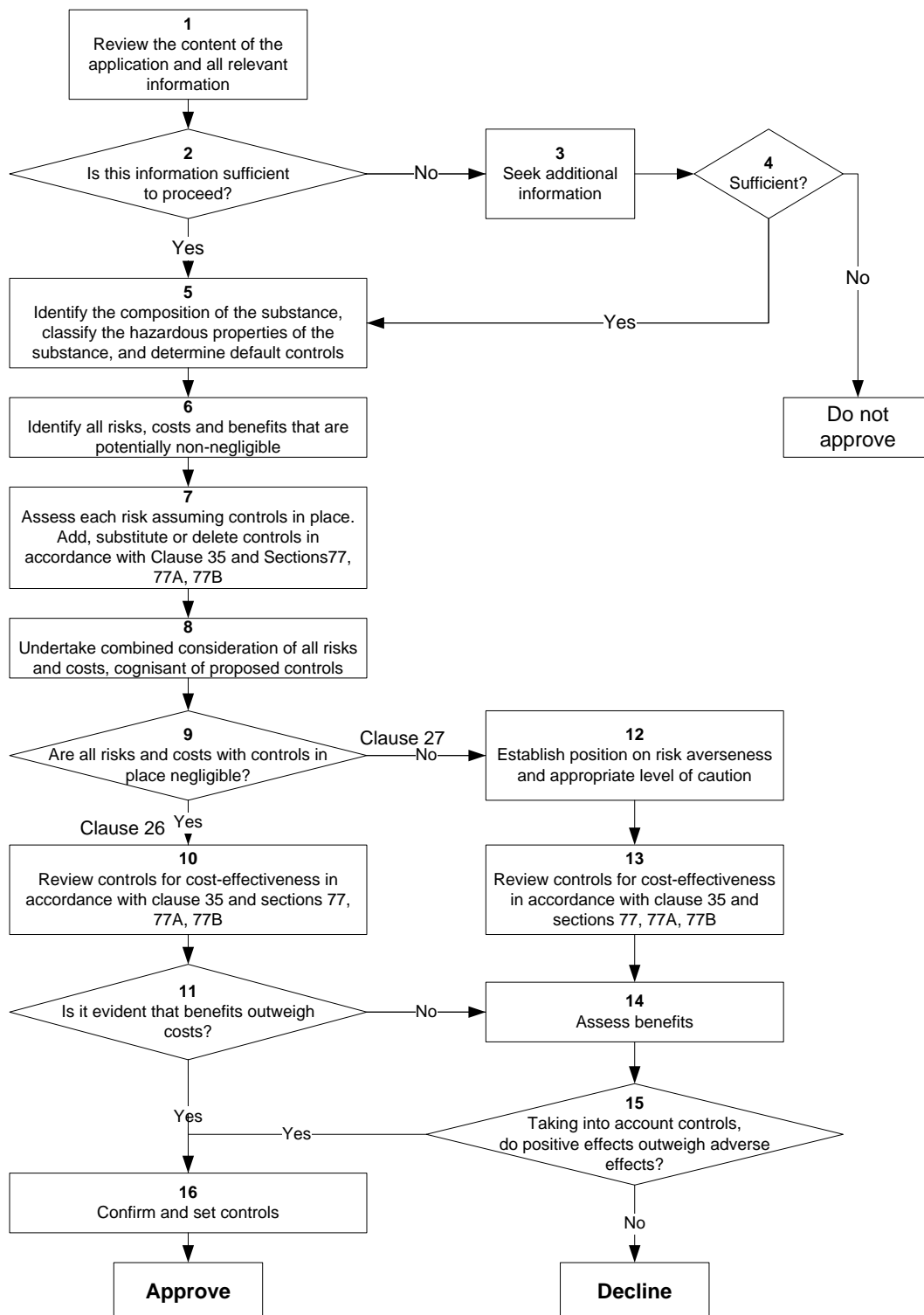
- Flowchart (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and
- Explanatory noted (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory noted provide a more comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

⁸ The HSNO decision maker refers to either the EPA Board or any committee or persons with delegated authority from the Board.

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For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory noted.



Explanatory Noted

Item 1:	Review the content of the application and all relevant information Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.
Item 2:	Is this information sufficient to proceed? Review the information and determine whether or not there is sufficient information available to make a decision. The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; i.e. information which is “necessary and sufficient” for decision-making.
Item 3:	(if ‘no’ from item 2) Seek additional information If there is not sufficient information then additional information may need to be sought from the applicant, the EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).
Item 4	Sufficient? When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application must be declined under section 29(1)(c).
Item 5:	(If ‘yes’ from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls Identify the composition of the substance, and establish the hazard classifications for the identified substance. Determine the default controls for the specified hazardous properties using the regulations ‘toolbox’.
Item 6:	Identify all risks, costs and benefits that are potentially non-negligible⁹ Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these ‘values’ are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as ‘sunk’ costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11). Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).

⁹ Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called ‘sunk’ costs since they are incurred whether or not the application is successful.

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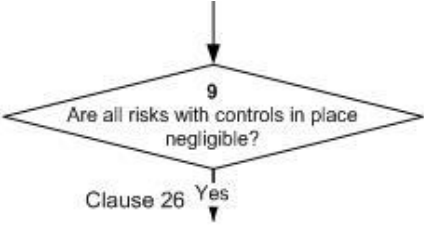
	Step 1:	<p>Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act¹⁰. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)).</p> <p>Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14).</p> <p>Consider short term and long term effects.</p> <p>Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.</p>
	Step 2:	<p>Document those risks, costs and benefits that can be readily concluded to be negligible¹¹, and eliminate them from further consideration.</p> <p>Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.</p>
Item 7:	<p>Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.</p> <p>The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place.</p> <p>Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of it occurring. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account.</p> <p>The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost.</p> <p>This assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)).</p> <p>Consider the HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls.</p> <p>See EPA report 'Approach to Risk' for further guidance¹².</p> <p>Where it is clear that residual risks are non-negligible and where appropriate controls are available,</p>	

¹⁰ Effects on the natural environment, effects on human health and safety, effects on Māori culture and traditions, effects on society and community, effects on the market economy.

¹¹ Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits.

¹² <http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf>

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	<p>add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 10 and 13</p> <p>If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.</p>
Item 8:	<p>Undertake combined consideration of all risks and costs, cognisant of proposed controls</p> <p>Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a 'basket' of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.</p>
Item 9:	<p>Are all risks with controls in place negligible?</p> <p>Looking at individual risks in the context of the 'basket' of risks, consider whether all of the residual risks are negligible.</p>
Item 10:	<div style="text-align: center;">  <pre> graph TD A[9] --> B{Are all risks with controls in place negligible?} B --> C[Clause 26 Yes] </pre> </div> <p>(from item 9 - if 'yes') Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B</p> <p>Where all risks are negligible the decision must be made under clause 26 of the Methodology.</p> <p>Consider the practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.</p>
Item 11:	<p>Is it evident that benefits outweigh costs?</p> <p>Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7.</p> <p>Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community.</p> <p>Consider whether there are any non-negligible external costs that are not associated with risks.</p> <p>If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs¹³. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant</p>

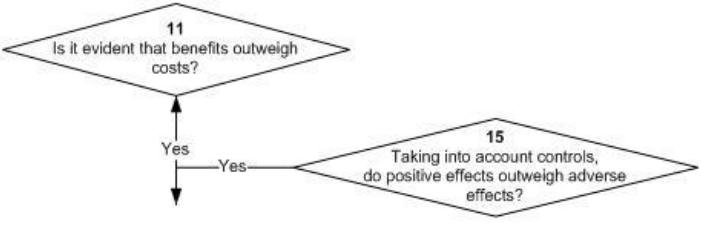
¹³Technical Guide 'Decision making' section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs. See also Protocol Series 1 'General requirements for the Identification and Assessment of Risks, Costs, and Benefits'.

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	<p>believes the benefits to be greater than the costs.</p> <p>However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 14).</p>
Item 12:	<div style="text-align: center;"> </div> <p>(if 'no' from item 9) Establish position on risk averseness and appropriate level of caution</p> <p>Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).</p>
Item 13:	<p>Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B</p> <p>This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 9 and 12).</p> <p>Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)).</p> <p>Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result.</p> <p>As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.</p>
Item 14:	<p>(if 'no' from item 11 or in sequence from item 13) Assess benefits</p> <p>Assess benefits or positive effects in terms of clause 13 of the Methodology.</p> <p>Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect.</p> <p>An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs¹⁴. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs.</p>

¹⁴ This principle derives from Protocol Series 1, and is restated in the Technical Guide 'Decision making'.

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	As for risks and costs, the assessment is carried out with the default controls in place.
Item 15:	<p>Taking into account controls, do positive effects outweigh adverse effects?</p> <p>In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13.</p> <p>Where this item is taken in sequence from items 12, 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology.</p> <p>Where this item is taken in sequence from items 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.</p>
Item 16:	 <pre> graph TD 11{11 Is it evident that benefits outweigh costs?} -- Yes --> 15{15 Taking into account controls, do positive effects outweigh adverse effects?} 15 -- Yes --> 16[] </pre> <p>(if 'yes' from items 11 or 15) Confirm and set controls</p> <p>Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.</p>

Appendix C: Direction under section 66 of the Act

Hazardous Substances (Dichlorvos-Containing Substances Direction Prohibiting Use and Controlling Storage and Disposal) Notice 2015

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

Notice

1. Title—

This notice is the Hazardous Substances (Dichlorvos-Containing Substances Direction Prohibiting Use and Controlling Storage and Disposal) Notice 2015.

2. Commencement—

This notice comes into force 28 days after the date of notification in the *New Zealand Gazette*.

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:

Collector means a person, other than the holder, who collects, transports or stores dichlorvos-containing substances, for the purpose of disposal, in accordance with this notice.

Decision Report means the decision report^{*} for the EPA reassessment application APP202097, lodged under section 63 of the Act.

Dichlorvos means dichlorvos (CAS Number 62-73-7).

Dichlorvos-containing substance means any of the following substances:

Flammable aerosol containing 3.1 g/litre dichlorvos and 8.7 g/litre propoxur, formerly approved under the Act with approval number HSR000207;

Ready to use liquid containing 4.4 g/litre dichlorvos and 9.6 g/litre propoxur, formerly approved under the Act with approval number HSR000209.

Environmentally sound disposal means disposal in accordance with clause 7 of this notice.

Holder means a person who is in possession of any dichlorvos-containing substances on or after the date this notice comes into force prior to collection by a collector.

4. Prohibition on use—

- (1) No person may use a dichlorvos-containing substance after the expiry of 15 March 2016.

5. Controls on use of dichlorvos-containing substances until 15 March 2016 —

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- (1) The controls set out in the Annex to the Decision Report shall apply to the use of a dichlorvos-containing substance from the date of commencement of this notice until the expiry of 15 March 2016.

6. Storage of dichlorvos-containing substances—

Holders and collectors must ensure that a dichlorvos-containing substance is only stored in suitable containers and kept in buildings and places which are:

- (a) secure and suitable for the purpose taking into account the quantities stored, moisture control ventilation and spill containment; and
- (b) sited so that the risk of contamination of people, animals, crops and the environment is minimised.

7. Controls on the disposal of dichlorvos-containing substances—

- (1) A dichlorvos-containing substance may be disposed of by:
 - (a) treating the substance using a method that changes the characteristics or composition of the substance so that the substance or any product of such treatment is no longer a hazardous substance; or
 - (b) exporting the substance from New Zealand as waste for environmentally sound disposal provided that such export complies with New Zealand law.
- (2) In subclause 7(1)(a), treating the substance does not include:
 - (a) application to or discharge to any environmental medium, save in the case of use of a dichlorvos-containing substance before the expiry of 15 March 2016 in accordance with the controls set out in the Annex to the Decision Report; or
 - (b) dilution of the substance with any other substance before discharge into the environment; or
 - (c) depositing the substance in a landfill or a sewage facility; or
 - (d) depositing the substance in an incinerator unless in doing so the substance is treated in accordance with subclause 7(1)(a).
- (3) All stocks of dichlorvos-containing substances must be disposed of by the expiry of 15 March 2016.

8. Controls on collectors of dichlorvos-containing substances—

- (1) A collector must ensure that equipment used to handle the substance complies with Regulation 7 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001.
- (2) A collector who handles a dichlorvos-containing substance must comply with Regulation 8 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001.

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- (3) Regulation 9 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001 applies to any quantity of a dichlorvos-containing substance.
- (4) For the purposes of Regulation 10 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001, no dichlorvos-containing substance in any quantity may be carried on any passenger service vehicle.
- (5) When stored for the purpose of environmentally sound disposal, a dichlorvos-containing substance must not be mixed with any other substance.
- (6) The Hazardous Substances (Packaging) Regulations 2001 apply to the substance “Ready to use liquid containing 4.4 g/litre dichlorvos and 9.6 g/litre propoxur” as if it is deemed to have a hazard classification that is class 6.1D and 9.1A.
- (7) The Hazardous Substances (Compressed Gases) Regulations 2004 apply to the substance “Flammable aerosol containing 3.1 g/litre dichlorvos and 8.7 g/litre propoxur” as if it is deemed to have a hazard classification that is class 2.1.2A.
- (8) The Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001 apply to the substance “Flammable aerosol containing 3.1 g/litre dichlorvos and 8.7 g/litre propoxur” as if it is deemed to have a hazard classification that is class 2.1.2A.
- (9) Transport of dichlorvos-containing substances by land within New Zealand shall comply with all relevant requirements of the Land Transport Rule: Dangerous Goods 2005 (Rule 45001/1).
- (10) Transport of dichlorvos-containing substances by sea within New Zealand shall comply with all relevant requirements of either the Maritime Rules: Part 24A – Carriage of Cargoes – Dangerous Goods (MR024A) or the International Maritime Dangerous Goods Code.
- (11) Transport of dichlorvos-containing substances by air within New Zealand shall comply with all relevant requirements of Part 92 of the Civil Aviation Rules.
- (12) The Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004 apply to dichlorvos-containing substances stored or transported in a tank, tank wagon or transportable container as those terms are defined in those Regulations.
- (13) The location and movement of dichlorvos-containing substances must be recorded in accordance with the Hazardous Substances (Tracking) Regulations 2001.
- (14) The Hazardous Substances (Emergency Management) Regulations 2001 apply to dichlorvos-containing substances as if they are deemed to have the following hazard classifications:
 - Flammable aerosol containing 3.1 g/litre dichlorvos and 8.7 g/litre propoxur: class 2.1.2A, 6.5B and 9.1A;
 - Ready to use liquid containing 4.4 g/litre dichlorvos and 9.6 g/litre propoxur: class 6.1D and 9.1A.
- (15) The Hazardous Substances (Identification) Regulations 2001 apply to dichlorvos-containing substances as if they are deemed to have the following hazard classifications:

Decision on the application for reassessment of dichlorvos and its formulations (APP202097)

Flammable aerosol containing 3.1 g/litre dichlorvos and 8.7 g/litre propoxur: class 2.1.2A,
6.3B, 6.4A, 6.5B, 6.7B, 6.9B, 9.1A, 9.4C;

Ready to use liquid containing 4.4 g/litre dichlorvos and 9.6 g/litre propoxur: class 6.1D, 6.3B,
6.4A, 6.5B, 6.7B, 6.9B, 9.1A, 9.3B, 9.4C.

Dated at Wellington this 15 day of September 2015.

Dr KERRY LAING, for and on behalf of the Environmental Protection Authority.

*Available online at <http://www.epa.govt.nz/search-databases/Pages/applications-details.aspx?appID=APP202097>

Appendix D: 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.
GAP	Good Agricultural Practice. GAP is an internationally recognised food safety tool for describing best practice for safe and effective chemical use.
HSNO	The Hazardous Substances and New Organisms Act 1996.
IPM	Integrated Pest Management involves the careful use of pest control techniques to discourage the development of pest populations and minimises the use of pesticides.
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.
Phytosanitary	Relates to the health of plants, especially with respect to the requirements of international trade.
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.
RPE	Respiratory Protective Equipment (a type of PPE).

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Risk

The combination of the magnitude of an adverse effect and the probability of its occurrence.

Annex: Controls for dichlorvos and its formulations

Under section 77(A)(4) of the Act, the Committee is able to impose controls in addition to the default controls triggered by the hazard classifications. The Committee considers that by imposing the additional controls outlined in Tables 21 and 22 of the Staff Update Report, that these additional controls are more likely to achieve the purpose of controls, that being to reduce or manage risk.

A full list of controls for each substance that has been approved in this decision is set out in an accompanying annex. The Controls Annex can be found on the EPA's website.