Staff report – The Modified Reassessment of Diazinon, Fenamiphos and Methamidophos

APP204199

MAY 2022

Executive summary

The Vegetable Research and Innovation Board (“the applicant”) applied for the reassessment of diazinon, fenamiphos and methamidophos under Section 63 of the Hazardous Substances and New Organisms Act (“the Act”, or “the HSNO Act”).

The applicant is seeking a reassessment of the approvals for substances containing diazinon, fenamiphos and methamidophos to amend the dates that these substances cease to be approved, such that these dates would be extended by an additional 10 years.

The reassessment application was received on 1 July 2021, and the Environmental Protection Authority (“EPA”) decided that the application would be progressed as a publicly notified, modified reassessment in accordance Section 63A of the Act.

The notification period for interested parties was open from 9 September 2021 to 8 November 2021. This timeframe included a 12 working day extension to the statutory submission period to account for the change of Covid-19 alert levels and ensure that submitters were able to adequately prepare their responses.

Twelve responses were received: four submissions self-identified as in support of the application, one was neutral, and seven were in opposition to the application. A subset (two) of those in opposition to the application requested greater restrictions be applied to the approvals for diazinon, fenamiphos and methamidophos. Of the submissions received, only industry submitters supported the application in its entirety. Of particular interest, the Ministry for Primary Industries (“MPI”) supported the retention of fenamiphos for biosecurity purposes but were neutral regarding the retention of methamidophos and did not express a position regarding the retention of diazinon. Four submitters asked to be heard.

Following receipt of the application the statutory timeframe for the application was waived under Section 59 of the Act and further information was requested under Section 52 of the Act.

The applicant did not provide any new information regarding the hazard classifications or risks associated with the application, stating they considered that the risks as assessed in the previous reassessment in 2013 were unchanged. No information was provided by the applicant or submitters to indicate that there has been a reduction in the risks associated with the use of diazinon, fenamiphos or methamidophos following the reassessment in 2013.

Submitters in opposition to the application indicated they considered that there were greater risks associated with the substances than assessed in 2013 and cited study information, primarily in the form of academic journal articles, in support of their position. The EPA considers that this information supports the risks as assessed in the previous reassessment and which was considered when setting the phase out of these substances. The EPA does not consider that there are greater risks associated with the substances than those previously determined.

The applicant indicated that there were significant benefits to the economy associated with the use of diazinon, fenamiphos and methamidophos and that the use of these substances is critical to the control of pests across several grower industries. The applicant and submitters in support of the application provided information regarding the economic value of the industries which claim to rely on these substances but did not illustrate the proportion of this value provided by diazinon, fenamiphos or methamidophos. The applicant did not explicitly monetise the benefits associated with the proposed

change, or the impacts to the benefits provided by industries which claimed to rely on these substances should the application be declined, and the approvals phased out.

MPI indicated in their submission that the commodities which require biosecurity treatment with fenamiphos are high risk and that there are currently no alternatives listed as approved treatments in the MPI Treatment Requirement: Approved Biosecurity Treatments (MPI-ABTRT). The use of fenamiphos in biosecurity as a dip treatment is associated with lower risks to human health and the environment when compared to dispersive applications for plant protection. We consider that the positive effects from the use of fenamiphos for biosecurity outweigh the risks and recommend the approval of the application to extend fenamiphos approvals for this use only.

The applicant provided limited information with which to assess the cultural impacts. Submissions and the EPA's Māori Perspectives Report consider that the changes sought by the applicant are likely to affect the ability and capacity of Māori to maintain their economic, social, and cultural wellbeing. The EPA's Māori Impact Assessments Report considered that the benefits associated with diazinon, fenamiphos and methamidophos to Māori were unlikely to outweigh the detrimental impacts to Māori and concluded that there was not sufficient new information to justify an extension to the phase out periods.

In assessing the available information summarised in this report, the EPA staff consider that there is not sufficient new information to illustrate that the positive effects associated with the applicant's proposal outweigh the risks of the extended use of these substances, except for the use of fenamiphos for biosecurity in accordance with the Biosecurity Act 1993. We recommend that the application is declined for the approvals for diazinon and methamidophos and that the approval for fenamiphos is extended for biosecurity use only.

Contents

1 Background

1.1 Diazinon, fenamiphos and methamidophos are organophosphate substances used as insecticides on a variety of crops as well as for biosecurity purposes.

1.2 Pesticides containing diazinon, fenamiphos and methamidophos were first approved under the Act on 15 June 2004 via the Hazardous Substances (Pesticides) Transfer Notice 2004.

1.3 Diazinon and methamidophos were approved as individual substances under the Act on 29 June 2006 via the Hazardous Substances (Chemicals) Transfer Notice 2006.

1.4 Diazinon, fenamiphos and methamidophos were reassessed as part of a larger reassessment of organophosphate and carbamate substances in 2013 following an application by the Chief Environmental Protection Authority ("EPA").

1.5 The 2013 reassessment was heard by a Decision-making Committee ("DMC").

1.6 The DMC considered the use of diazinon, fenamiphos and methamidophos to have significant non-negligible risks to human health and the environment, such that their approvals should be declined. The risks for home users associated with these substances was considered to outweigh the benefits and these use patterns were declined.

1.7 The DMC also considered that significant benefits would be derived from plant protection and biosecurity uses, and that there was a lack of effective alternative substances available for critical use patterns. The DMC therefore decided to set extended phase out periods which would allow for transition to other replacements.

1.8 Fenamiphos and methamidophos containing substances were set to have their approvals expire in 2023 while diazinon containing approvals were set to decline in 2028.

1.9 In 2020 the Vegetable Research and Innovation Board ('the applicant') applied for grounds to reassess diazinon, fenamiphos and methamidophos (APP203975). Evidence was provided regarding the positive effects associated with the substances, namely that it was considered that there was a lack of viable alternatives to plant protection products containing diazinon, fenamiphos or methamidophos where such alternatives were anticipated in the outcome of APP201045 to be available at the time of phase out. These grounds were granted by a DMC on 8 May 2020.

2 Process, consultation and notification

Lodgement and formal receipt

2.1 The reassessment application was lodged on 22 February 2021. It was formally received on 1 July 2021. In their application to reassess diazinon, fenamiphos and methamidophos the applicant sought to review the benefits assessment applied in the 2013 decision with the aim of extending the approval timeframe for these substances for a further 10 years.

Scope of application

2.2 The Chief Executive of the EPA considered the content of the application and decided to use the EPA's discretionary power in Section 63A(1) of the Act to proceed with the application as a modified reassessment. The Chief Executive decided that the scope of the modified reassessment would be limited to an assessment of the following:

- hazard classifications
- benefits, in particular in relation to the availability of alternatives
- time limitations on the approvals
- the risks associated with the use of the substances
- any interim controls required to manage the substances until the expiry date of the time limited approval.

2.3 As a modified reassessment, the outcome of this application may vary the EPA controls that are attached to a hazardous substance, or the description of a hazardous substance, or both; but it may not revoke an approval given to a hazardous substance[1].

2.4 The applicant proposed that specific approvals as listed in their application be subject to this reassessment, these being approvals which currently have registrations under the Agricultural Chemicals and Veterinary Medicines Act (ACVM Act) and are therefore known to be in use. They stated they do not wish to have unused approvals reviewed in this reassessment and that those approvals should instead lapse.

2.5 As the application purpose is for the reassessment of diazinon, fenamiphos and methamidophos and therefore allows for the reassessment of all those substances, the EPA's Chief Executive used his discretion as the decision maker to include all approved substances with these active ingredients in the reassessment. The full list of approvals subject to this decision are listed in Appendix A.

Further information requests and time waivers

2.6 Prior to public notification of the application, it was determined that further information regarding the applicant's proposal was required. Information was requested from the Vegetable Research and Innovation Board under Section 52 of the Act and the time frame for public notification of

[1] See Section 63A(2) of the Act.

this application was waived under Section 59 of the Act. The timelines for this time waiver were mutually agreed between the EPA and the applicant.

2.7 This information request was made on 12 July 2021, the applicant responded on 6 August 2021. The information request and the response were made available online on the application register for this reassessment.

2.8 We note that the applicant's response did not address multiple aspects of the information request and reiterates the applicant's intent to have the risk assessment and benefits assessment from the previous reassessment maintained, with the relative weighting reviewed in light of the claim there are no viable alternatives.

Notification of application

2.9 Subsequently, the chief executive decided to not use the EPA's discretionary power in Section 63A(4) of the Act to process the application without public notification. The application was, therefore, publicly notified in accordance with Section 53 of the Act.

2.10 The application was publicly notified on 9 September 2021.

2.11 To account for the potential impacts on the ability to prepare material for submissions as a result of the Covid-19 alert levels at the time of public notification the EPA decided to apply a time extension of 12 days to the closure of submissions. The application was therefore open for submissions until 8 November 2021.

Response from other government agencies

2.12 The Ministry for the Environment, the Ministry of Health, the Ministry for Primary Industries (MPI), and the Department of Conservation were advised of the application and notified of the submission period.

2.13 MPI provided a response in the form of a submission. The Ministry of Health and the Ministry for the Environment did not provide a response to this application.

2.14 WorkSafe New Zealand (WorkSafe) has worked closely with the EPA project team. Their comments will be provided in their standalone report.

Proposed amendments of Re-entry intervals

2.15 During the timeframe of this application WorkSafe has initiated consultation regarding a proposal to amend the re-entry intervals (REIs) for a group of hazardous substances including diazinon, fenamiphos and methamidophos. This process is independent of the HSNO modified reassessment application process.

2.16 While we cannot pre-empt the final decision on the review of REI values, we do note that the REIs proposed for diazinon, fenamiphos and methamidophos all represent significant increases in the respective values which were set during the 2013 reassessment of these substances. While we are not able to definitively state the practical implications of these proposed REIs

coming in to force, there may be implications of the practical usability of these substances with longer REIs resulting in impacts to the benefits associated with their use.

Information sources

2.17 In preparing this report, the following documents and information were considered:

- The application form, including appendices
- Confidential material submitted by the applicant with the application form
- Additional information from the applicant
- Additional information from Ministry for Primary Industries
- The submissions
- Information received from WorkSafe
- EPA Māori Impact Assessment Report
- The 2013 Organophosphates and Carbamates Reassessment (APP201045) including associated reports
- Novachem New Zealand Agrichemical Manual[2]

[2] https://www.novachem.co.nz

3 Applicants' proposal

3.1 The Vegetable Research and Innovation Board has requested that the approvals containing diazinon, fenamiphos and methamidophos be reassessed to extend the time limited approvals. They have requested the benefits assessed in the previous reassessment be reviewed, stating that the assumption that replacement substances would become available over the phase out time set for these approvals as anticipated in the decision, has not been realised.

3.2 They state that there remains significant benefit to these substances remaining available and that there would be significant impacts should the substances become unavailable at the current expiry date of the time limited approvals.

3.3 They propose the following changes to the time limited approvals

- Fenamiphos and methamidophos approvals to expire in 2033.
- Diazinon approvals to expire in 2038.

3.4 The applicant proposed that specific approvals as listed in their application be subject to this reassessment, these being approvals which currently have registrations under the Agricultural Chemicals and Veterinary Medicines Act (ACVM Act) and are therefore known to be in use. They stated they do not wish to have unused approvals reviewed in this reassessment and that those approvals should instead lapse.

3.5 As the application purpose is for the reassessment of diazinon, fenamiphos and methamidophos and therefore allows for the reassessment of all those substances, the EPA's chief executive used his discretion as the decision maker to include all approved substances with these active ingredients in the reassessment. This decision was outlined in the pathway decision.

3.6 The applicant proposed not to review the risks associated with these approved substances stating that they consider the risk assessment undertaken in 2013 for the previous reassessment (APP201045) to still be applicable such that review or update to the risk assessment is not required. In alignment with this statement, they did not provide a risk assessment, nor any review or summary of updates to the risks associated with the substances in the application, or in response to the information request.

3.7 The applicant provided limited new evidence regarding the benefits associated with the proposed change to the approvals, and the continued use of the substances beyond the current phase out date of their approvals. Again, the applicant noted that they were not seeking to have the majority of the benefits assessment from the previous reassessment reviewed, but rather that relative weighting of the benefits be reconsidered in the context of their claims that there lacked effective alternative substances as replacements for the use patterns of diazinon, fenamiphos and methamidophos.

3.8 The applicant provided information regarding the crops which each substance was used on, and the pests which the substances were used to control (table 6 of the application). However,

they did not illustrate which pest species were controlled on which crop nor which use patterns were considered crucial or to not have any effective replacement.

3.9 The applicant provided information pertaining to the Gross Domestic Product ("GDP") values for each crop or use pattern on which the substances are used. As part of this information, they provided information on the number of growers, the area utilised for crop production and the volume of growth. This information also included information on the number of people employed in each grower industry both directly and in packhouses.

3.10 The application lists several new insecticide active ingredients which have been approved in New Zealand following the 2013 reassessment, noting that these substances have few uses against the pests which they have identified as critical use patterns for diazinon, fenamiphos and methamidophos.

3.11 The applicant provided summary information from industry bodies (Citrus NZ and The Foundation for Arable Research), regarding critical pests for control and research into alternatives to diazinon, fenamiphos and methamidophos. These summaries address both biocontrol and chemical methods of pest control.

3.12 Regarding biocontrol-based alternatives, they indicate that while candidates have been identified, these candidates either have practical limitations or require further research to address issues with implementation including with production, application methodology and efficacy timeframes relative to crop turnover such that these methods of control are currently considered unsuitable.

3.13 This supporting information also outlined research work regarding the investigation of new candidates for chemical control of these critical pests, however, the information noted issues with implementation including costs associated with regulatory data requirements or potential supply issues for substances with limited use or regulatory constraints in international jurisdictions.

3.14 Based on their assessment of new substances and the research undertaken towards new candidates, the applicant proposes that there has not been sufficient development of new alternatives which they state were envisioned in setting the phase out periods for diazinon, fenamiphos and methamidophos. They consider that this supports an extension to the phase out period of the three substances.

3.15 In supporting a requested extension of 10 years to each phase out date, the applicant has identified the implementation of the 'Lighter Touch' research and development scheme which commenced in 2020, as well as the development of RNAi technologies as the key opportunities for the development of new insecticides.

3.16 They anticipate that the research and development in these two areas will result in new control options over the next five to 10 years. They anticipate that any new substances will take up to four years to generate regulatory data and receive EPA and ACVM approval. Based on this anticipated timeline they estimate new substances to be available around 2031, such that a 2033 expiry timeframe would allow for a two-year transition time where supplies of fenamiphos and methamidophos are phased out.

3.17 In response to a request for further information under Section 52 of the Act, the applicant supported their proposal for a 10-year extension to the phase out date for diazinon to 2038. They cited claims regarding increasing timeframes and difficulty to approval and registration of new substances in New Zealand. They also indicated that an extension of five years, resulting in a phase out in line with that proposed for fenamiphos and methamidophos would still provide opportunities to identify replacements. No information specific to diazinon was provided.

4 Submissions

Submitters

4.1 Twelve submissions were received for this application (see Appendix C for the full list of submitters). Four of these submitters identified that they wished to present on behalf of their submission at a hearing.

4.2 In their submissions, seven submitters self-identified to be in opposition to the applicant's proposal, four were in support and one neither supported nor opposed the application.

Position	Submissions		Want to be heard at a hearing	
	Number	Percentage	Number	Percentage*
Oppose proposal	7	58.3%	3	25
Oppose proposal with additional restrictions**	2	16.7%	1	8.3
Neutral	1	8.3%	0	0
Support proposal	4	33%	1	8.3
Total	**12**	**100**	**4**	**33.3**

* of total submissions
** As a subset of those who oppose the proposal

4.3 The EPA has used the information gained from submissions, where relevant, to inform the evaluation of the application. Key issues raised in submissions are highlighted below. The views summarised are those of submitters, as organised by the groupings in **Error! Reference source not found.**1; they do not represent the view of the EPA.

Oppose proposal

4.4 Seven submitters opposed the application to extend the importation, manufacture, and use of diazinon, fenamiphos and methamidophos. These submitters all cited the risks to human health and the environment of the continued use of these substance as the reason for the opposition to the proposal.

4.5 These submitters consider that the economic benefit derived from the use of diazinon, fenamiphos and methamidophos is outweighed by the environmental cost resulting from the toxicity of the substances.

Alternative substances:

4.6 Most submitters disputed the applicant's statement that diazinon, fenamiphos and methamidophos were critical to the control of the pests identified in table 6 of the application. These submitters considered that there are alternative substances including biological controls which had been developed which were sufficient to replace diazinon, fenamiphos or methamidophos and there was therefore, not a compelling basis for the reassessment.

4.7 Te Runanga o Ngāi Tahu HSNO Committee ("Ngāi Tahu") stated that while there were limited broad spectrum replacements, they consider suitable alternatives exist which are softer and more targeted than organophosphates.

4.8 The Environmental Law Initiative ("ELI") cited alternatives to the control of greenhouse thrips and Australian Citrus Whitefly as examples of critical pests which could be controlled by alternative substances and stated that there are further examples, requesting that the EPA scrutinise the applicant's claims. Furthermore, they also identified that the organophosphates subject to this reassessment are not proposed for use in biosecurity treatment of brown marmorated stink bug.

4.9 Other submitters (Physicians and Scientists for Global Responsibility ("PSGR"), The Soil & Health Association of New Zealand Inc ("Soil and Health") NZ, and GE Free Northland (in Food and Environment) ("GE Free")) indicated they believed that non-chemical interventions would be able to be used to replace pest control methods.

4.10 Submitters also stated that it was not clear which organophosphates are critical for which crops, or which target crops/ pests have no suitable alternatives to the three substances which are the subject of this reassessment.

Absence of independent information:

4.11 Most submitters who opposed the application expressed concern that the applicant has not provided any new information on the risks or safe use of the substances. They stated that as there have been studies on the human health and environmental impacts of the substances following the previous reassessment, they consider the 2013 risk assessment to no longer be adequate.

4.12 Three submitters (Soil and Health, PSGR and ELI) indicated they considered that there was a lack of independent scientific information available regarding the effects of the substances, and whether there are effects specific to the taxa present in the New Zealand environment. They identify regulatory evaluations of diazinon (United States EPA, 2017) and fenamiphos (European Food Safety Authority, 2019), stating that these assessments highlight data gaps regarding the effects of the substances and their environmental fate.

4.13 In considering the absence of data ELI stated that the precautionary principle should be applied such that an earlier phase out of diazinon, fenamiphos and methamidophos should occur.

International Regulatory position:

4.14 Multiple submitters identified the regulatory positions on diazinon, fenamiphos and methamidophos taken by international regulators. It was highlighted that none of the three substances are approved in the European Union. Soil and Health highlighted the European Union decision to not renew the substances was due to operator and bystander risks as well as short and chronic dietary exposure in pome fruits.

4.15 ELI identified that fenamiphos products were prohibited by the United States in 2014. While registrations for methamidophos were voluntarily cancelled by the registrant.

4.16 Several submitters also noted that methamidophos was listed under the Rotterdam convention.

Human Health risks associated with diazinon, fenamiphos or methamidophos

4.17 The submitters opposing the application expressed concerns regarding the human health risks associated with the substances.

4.18 Multiple submitters identified that the International Agency for Research on Cancer ("IARC") listed diazinon as a group 2 probable carcinogen in 2015.In relation to this, Te Runanga o Ngāi Tahu HSNO Committee (Ngāi Tahu) highlighted that Māori had higher cancer rates and higher mortality and identified that there were higher risks of whanau interacting with pesticide residues as many mahinga kai sites are adjacent to rural agriculture.

4.19 PSGR and Soil and Health expressed concern regarding risks from neurotoxicity and endocrine disruption. Soil and Health also claimed that methamidophos causes birth defects and increases the risk of certain cancer types.

Environmental risks associated with diazinon, fenamiphos or methamidophos

4.20 All submitters opposing the reassessment expressed concerns about environmental contamination of organophosphates and adverse effects to ecosystems including impacts to the aquatic environment, as well as to non-target and beneficial invertebrates.

4.21 Fish and Game New Zealand expressed the variability of degradation across different environmental conditions not being accounted for and that withholding periods were difficult to enforce at the paddock scale for birds. They therefore stated that continued use of these substances risked collateral damage to avian, insect and aquatic ecosystems.

4.22 Ngāi Tahu identified concerns regarding downstream effects from broad spectrum insecticides such as removal of food source for taonga species, and unchecked pest species growth. They state that studies have shown diazinon to have a significant impact on beneficial insects and to be highly toxic to zoo plankton. They further state that fenamiphos and methamidophos act on the same pathway and would have similar impact. Ngāi Tahu also expressed general concern for species loss as a result of chemical overburden in the environment.

4.23 Soil and Health and Ngāi Tahu drew attention to the Institute of Environmental Science and Research ("ESR") survey which identified the presence of diazinon in water from wells in of the Canterbury region and recommended that ground water impacts should be reviewed in any risk assessment.

Te Ao Māori

4.24 In their submission Ngāi Tahu note their position as kaitiakitanga and partners to Te Tiriti o Waitangi noting their role to consider the impact on taonga to the environment, the cultural acceptability of any activity in the environment and obligations to consult with Ngāi Tahu as a Tiriti partner regarding any potential impacts on taonga in the Ngāi Tahu takiwa.

4.25 Ngāi Tahu further expressed disappointment that the applicant did not follow up a request for consultation with Māori. They criticise the application for failing to discuss the impact of

continued use of the reassessment substances on taonga species and for instead relying on the assessment undertaken eight years prior.

4.26 Ngāi Tahu highlight in their submission, the interconnectedness of health with the environment and the importance that mahinga kai and rongoa sources remain free of toxins.

4.27 Fish and Game drew attention to the concept of Te Mana o te Wai from the National Policy Statement for Freshwater Management and its emphasis on the health and wellbeing of water bodies and freshwater ecosystem. They state that to give effect to Te Mana o Te Wai would require embedding in all environmental regulation, and that prompt disuse of the organophosphate substances would give effect to this.

Oppose proposal and propose additional restrictions

4.28 Of the submitters in opposition to the reassessment, two submitters (ELI and Fish and Game NZ) proposed that the phase out period for diazinon be reduced by five years to 2023 in line with the current phase out dates for fenamiphos and methamidophos.

4.29 Fish and Game also requested additional restrictions be applied to the substances until their phase out. They seek controls which address the risks to waterfowl and other non-target species, and which account for the impacts changing climate and weather patterns have on these risks.

New risk information

4.30 ELI and Fish and Game rejected the applicant's claim that the risk assessment of the use of these substances as undertaken in 2013, is unchanged and would not require update. They cited scientific and regulatory literature published since the last reassessment for each of the active ingredients regarding the risks to waterfowl, predatory birds, non-target insects and aquatic ecosystems.

4.31 Fish and Game expressed particular concern regarding the risks to waterfowl from diazinon acting as an acetyl cholinesterase inhibitor. They also stated that organophosphate exposure may also result in sublethal effects for different avian species at lower concentrations.

4.32 Fish and Game provided information regarding observed effects and changes to waterfowl populations in New Zealand which they connected to diazinon exposure and identified specific examples of poisoning incidents where significant waterfowl deaths had occurred. In some instances, they state that diazinon was deliberately applied to poison birds.

Absence of a benefit and cost assessment:

4.33 ELI noted that the application does not assess the cost impacts of continued use of the substances. They identified literature which indicated that the costs of human health effects from exposure to organophosphates is estimated at $44.7 billion (USD) in the United States and $194 billion (USD) in the European Union and they state that these costs were likely to be significant in New Zealand.

4.34 Similarly, they also noted the lack of an economic assessment of the contribution of the substances to the yield of the target crops and therefore the economic benefits directly derivable from the use of these substances and impacts of their unavailability.

4.35 ELI therefore recommended that an analysis of economic costs be commissioned to review the benefits and cost impact of the continued use of the substances subject to the reassessment.

Neutral

4.36 The Ministry for Primary industries ("MPI") identified biosecurity uses for both fenamiphos and methamidophos. They stated that diazinon is not an approved treatment option for goods at the border in the MPI Treatment Requirement: Approved Biosecurity Treatments (MPI-ABTRT).

4.37 MPI noted that fenamiphos remains the only treatment option for nematodes at the border and is therefore of critical use. They did however note that data from 2014-2021 indicated that fenamiphos treatment was rare and attributed this to the identification of pests prior to treatment increasing making some treatments now unnecessary. They identify the risks associated with the use of fenamiphos and outline practical actions to mitigate risk undertaken by nursery owners who use the substances, and border staff inspecting treated plants.

4.38 MPI state that the use of methamidophos is a recommended treatment under the MPI-ABTRT for the treatment of fresh flowers and foliage is recommended under treatment code FNS7 and outline the treatment protocol. They note that a half of contact insecticides and all systemic insecticides are no longer registered in Europe such that treatment is likely to occur on arrival in New Zealand rather than pre-departure.

4.39 However, they note that shipments are rarely directed for treatment under FNS7 and when they are they are not treated with methamidophos. They state that they consider the use of methamidophos less critical than fenamiphos as multiple options for treatment exist.

4.40 In response to the applicant's suggestion that diazinon and methamidophos may be used in response to an incursion of brown marmorated stinkbug (BMSB), MPI note that these were not currently proposed for this use in the current MPI BMSB Operational Specification. MPI stated that due to the health risks associated with the use of these substances, that it would be unlikely for these to be the preferred treatment options for brown marmorated stinkbug.

Support proposal

4.41 Four submitters supported the proposal to extend the approval time for the substances. Three submitters, Nufarm Limited (Nufarm), Federated Farmers of New Zealand (Federated Farmers) and Agrisource Limited (Agrisource) provided additional information in support of their position. Orion Agriscience also supported the application but did not provide further information or comment in support of their position.

4.42 Nufarm, Federated Farmers and Agrisource all expressed concern regarding a lack of viable insecticide alternatives and requested an extension to the phase out to allow for research and implement alternative pest control substances. Agrisource expressed that they understood the need to review these substances and would work alongside key stakeholders to review

restrictions on methamidophos to support its ongoing use where there are very limited alternatives.

Support for the extension of diazinon approvals.

4.43 Two submitters (Nufarm and Federated Farmers) expressed support for the extension for diazinon, highlighting that it is highly effective for controlling grass grub and that this is critical for pasture and crops in New Zealand.

4.44 They note that grass grub can be significantly damaging to pasture and arable sectors as well to cereals, carrots, herbage seed and white clover seed crops and noted that these industries have significant value to export revenue and GDP to New Zealand. Nufarm Limited (citing the Foundation of Arable Research) state that a 10% loss of yields from reduced control of grass grub would cost about $32 million in farm returns.

4.45 These submitters consider diazinon to be the only agrichemical option for planting control of grass grub and grass grub larvae in arable crops, stating that they are not aware of other viable alternative chemistry or that there is not an alternative available in the market which would sufficiently control grass grub to the level it is controlled with diazinon.

4.46 Nufarm state that finding alternatives to diazinon for the control of grass grub is difficult as grass grub is a New Zealand native pest, and it is difficult to assess whether a product developed overseas will be efficacious. They also state that many of the new compounds that are being investigated as alternatives are not registered in pastures and crops for livestock and there is a data gap regarding animal transfer residue data and grazing withholding periods. They note that they have provided detailed information regarding efforts to seek alternatives as part of the applicant's confidential appendix.

Support for the extension of methamidophos approvals.

4.47 Two submitters supported the proposal to extend the approvals for methamidophos. They highlighted use for the treatment of maize, sweetcorn, and potatoes to protect yields against green vegetable bug and potato tuber moth, with Federated Farmers noting the use of maize in the production of grain for feed for the pastural and livestock sectors.

4.48 Conflicting statements were provided by submitters regarding the frequency of use of methamidophos. Agrisource indicated that methamidophos was used frequently by sweetcorn and potatoes growers, while Federated Farmers expressed an understanding that the substance is not frequently used but is a valuable tool for green vegetable bug control.

4.49 In addition to highlighting existing uses, Federated Farmers also considered that methamidophos should be retained as tool for future biosecurity incursions, highlighting potential use against disease-carrying thrips or armyworms across a range of crops. They note that MPI anticipates the arrival of fall armyworm in the next five years.

Support for the extension of fenamiphos approvals

4.50 No submitters who indicated in their submission as being in support of the application indicated express support for the retention of fenamiphos.

EPA response to submissions

4.51 Several submitters in opposition to the reassessment application identified the ESR report which indicates presence of diazinon in Canterbury waterbodies and stated that the information indicates that there is groundwater movement or contamination with diazinon.

4.52 The EPA notes that the ESR report itself states, “The detection of other pesticides such as DDT, diazinon and atrazine, which have very different leaching characteristics (Table 6) support contamination of the well from surface sources rather than widespread groundwater contamination.” Noting this statement from the report and the leaching and soil adsorption properties of diazinon which indicates groundwater contamination should not occur, the EPA has determined that a review of the groundwater risks associated with diazinon is not required.

4.53 Several submitters referenced study or regulatory information regarding the human health and environmental risks associated with the substance. The EPA has reviewed this material and addressed the risks associated with diazinon, fenamiphos and methamidophos in section 7 of the report.

4.54 We note that the request from Fish and Game for restrictions and guidance to reflect the differing effects of climate and weather on the effects of exposure to these substances. the application of nuanced controls to reflect use in specific locations or environments within New Zealand could not be readily set for an approval which covers use across New Zealand. Such conditions could be applied through more localised assessment using Permissions under Section 95A of the Act. This is discussed further in section 13.

4.55 The EPA acknowledge the key concepts of kaitiakitanga, Te Tiriti partnership and Te Mana o Te Wai as highlighted by Ngai Tahu and Fish and Game submissions. The EPA also has expressed concern regarding the lack of assessment and engagement by the applicant regarding the impact on Māori cultural receptors of continued use of diazinon, fenamiphos and methamidophos.

4.56 Prior to the submission period the EPA sought to address this point through an information request to the applicant under Section 52 of the Act. However, the applicant was not able or not willing to meet the requirements of the information request on this matter. We note that iwi have the opportunity to engage and provide input to the application in the submission process. We have sought to address risks to te Ao Māori in our Māori impact assessment (section 9); however, we recognise that this is not a replacement for meaningful engagement by the applicant.

4.57 In their submission, the ELI referred to the estimated annual human health costs in the United States and European Union associated with exposure to organophosphates. However, it is not clear what contribution to these costs is attributable to diazinon, fenamiphos or methamidophos, and we note that these figures do not include per capita values. While we appreciate the concern regarding these health costs, it is not apparent as to how these figures translate to a New Zealand context.

5 International obligations

5.1 Under Section 6 of the Act, to achieve the purpose of the Act, all decision makers must take into account New Zealand's international obligations (among other considerations).

5.2 New Zealand does not have any international obligations specific to the continued use of diazinon or fenamiphos or any substances containing these active ingredients.

5.3 Methamidophos is listed under Annex III of the Rotterdam convention. Annex III chemicals are pesticides and industrial chemicals which have been banned or severely restricted due to health or environmental reasons. The movements of hazardous chemicals listed in Annex III are subject to the Prior Informed Consent procedure ("PIC procedure") where exports are only permitted if the importing state has consented to the future import of that specific chemical.

5.4 There are no other international obligations regarding the import, manufacture, or use of methamidophos.

6 Hazardous properties

6.1 When diazinon and methamidophos were transferred in 2006 to the Act they had the following classifications:

- Diazinon: 6.1C, 6.8B, 6.9A, 9.1A, 9.2D, 9.3A, 9.4A
- Methamidophos: 6.1B, 6.4A, 6.9A, 9.1A, 9.2B, 9.3A, 9.4A

6.2 Fenamiphos did not have its own approval during the transfer of substances to the Act, however the following classification was used to determine the classifications for substances containing fenamiphos prior to the 2013 reassessment:

- Fenamiphos: 6.1B, 6.4A, 6.9A, 9.1A, 9.2B, 9.3A, 9.4A

6.3 In the 2013 reassessment the following classifications were applied to update the classifications for individual substances containing these active ingredients:

- Diazinon: 6.1C, 6.8B, 6.9A, 9.1A, 9.2B, 9.3A, 9.4A
- Fenamiphos: 6.1B (oral), 6.1B (dermal) 6.1C (inhalation), 6.4A, 6.9A (oral, dermal and inhalation), 9.1A, 9.2D, 9.3A, 9.4A
- Methamidophos: 6.1B (oral), 6.1B (dermal), 6.1B (inhalation), 8.2C, 8.3A, 6.9A, 9.1A, 9.2B, 9.3A, 9.4

6.4 In April 2021 individual approvals of hazardous substances were reissued to apply the GHS classifications. Methamidophos was subject to reissue with the following classifications applied.

- Methamidophos: Acute Oral Toxicity Category 2, Acute Dermal Toxicity Category 2, Acute Inhalation Toxicity Category 2, Skin Corrosion Category 1C, Serious Eye Damage 1, Specific Target Organ toxicity – Repeated Exposure Category 1, Hazardous to the Aquatic Environment Acute Category 1, Hazardous to the Aquatic Environment Chronic Category 2

6.5 The approval for diazinon as an active ingredient was revoked in this reissue, while fenamiphos as an active ingredient has never held an individual approval. The following classifications were used in the reissue of substances containing these active ingredients:

- Diazinon: Acute Oral Toxicity Category 3, Acute Dermal Toxicity Category 3, Acute Inhalation Toxicity Category 4, Reproductive Toxicity Category 2, Specific Target Organ toxicity – Repeated Exposure Category 1, Hazardous to the Aquatic Environment Acute Category 1, Hazardous to the Aquatic Environment Chronic Category 1
- Fenamiphos: Acute Oral Toxicity Category 2, Acute Dermal Toxicity Category 2, Acute Inhalation Toxicity Category 3, Eye irritation Category 2, Specific Target Organ toxicity – Repeated Exposure Category 1, Hazardous to the Aquatic Environment Acute 1, Hazardous to the Aquatic Environment Chronic Category 1, Hazardous to the Terrestrial environment.

6.6 No changes to the classifications for any of these substances are proposed by the applicant.

6.7 The EPA notes information provided by submitters on the application and has reviewed the supporting information cited in these submissions. We do not propose any changes to the hazardous classifications for diazinon, fenamiphos or methamidophos based on this information.

7 Risk assessment

Preamble

7.1 The applicant has not provided new information towards the hazardous effects or risks associated with the use of the substances.

7.2 Instead, the applicant has requested that the risks associated with the use of these substances are not reviewed but rather the existing assessment of the risks associated with these substances as undertaken in the 2013 reassessment be applied to the current reassessment.

Lifecycle

7.3 During the importation, transportation, and storage of these substances, it is expected that exposure is unlikely to occur and that the proposed controls and other legislative requirements will sufficiently mitigate the risks associated with these stages of the substance lifecycle to a negligible level. These include the existing EPA Notices around packaging, identification, and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994, and the Health and Safety at Work Act 2015.

7.4 It is considered that there is the potential for exposure to humans and the environment to occur during the use phase of the substances, with potential exposure to the environment possible, following disposal. These risks have been considered further in this evaluation.

7.5 The existing controls and legislative requirements were considered when identifying controls to mitigate risks associated with use of the substance.

Use pattern

7.6 Diazinon, fenamiphos and methamidophos are insecticides for plant protection in various crops and for biosecurity treatment of pest species. The applicant has highlighted a number of crucial crops species and/or pest species for which these substances are considered critical in table 6 of their application.

7.7 The substances are primarily applied as plant protection products using broadcast and spot directed spray use patterns. Dip treatment may also occur for biosecurity treatment. Diazinon, fenamiphos and methamidophos are used by professional users only. Diazinon substances for home use were reassessed and revoked in 2016 as an outcome of the Reassessment of carbaryl, chlorpyrifos and diazinon used in veterinary medicine and other non-plant protection purposes (APP202098).

7.8 In the 2013 reassessment the use of diazinon, fenamiphos and methamidophos for plant protection were identified to pose significant risks to human health and/or the environment such that the approvals for these substances were set for revocation in the 2013 reassessment. An extended phase out period was applied to account for significant benefits associated with these

substances and to allow industry to invest in the development and implementation of replacement substances.

2013 reassessment

Human health effects

7.9 The 2013 reassessment concluded there were significant risks associated with exposure to diazinon, fenamiphos and methamidophos. We have highlighted key aspects of the risk assessment regarding adverse effects to human health below.

Diazinon

7.10 The 2013 risk assessment found **non-negligible** risks to human health with most of the use scenarios assessed (70 of 95 use scenarios modelled). Most use scenarios for diazinon were considered to pose a **low** (56 use scenarios) or **medium** (17 scenarios) risk to operators, this was counterbalanced by an increase in risk to re-entry workers (24 **low** and 43 **medium** risk scenarios), even with the application of controls.

7.11 Most use scenarios were found to be associated with a **low** level of risk to bystanders (65 of 95 scenarios modelled). These scenarios still present Risk Quotient (RQ) values above the EPA's level of concern (RQ value >1) with controls applied and are still considered **non-negligible**. The risk assessment highlighted that exposure to bystanders could potentially result in harmful effects such as neurotoxicity.

Fenamiphos

7.12 The previous reassessment found **medium to high** risks to operators and **low to medium** risks to bystanders for the majority of use scenarios for fenamiphos for plant protection, where the substances are applied under dispersive uses through boom spray. The lowest Risk Quotient (RQ) values derived for boom spray application significantly exceeded the level of concern (Carrots scenario 8, operator full PPE and RPE RQ = 64, bystander RQ = 62).

7.13 While still presenting a **low** risk, the use of fenamiphos in biosecurity facilities through dipping use patterns present lower risks to operators (with full PPE and RPE RQ = 20) than dispersive use patterns where the substance is applied by boom. Furthermore, no exposure occurs for re-entry workers or bystanders such that the risks are considered **negligible**.

Methamidophos

7.14 The 2013 reassessment found **low** (8 scenarios) to **medium** (10 scenarios) risks to operators in the use phase. 18 of 20 scenarios modelled found **medium** risks in the re-entry phase of methamidophos uses, with no uses presenting **negligible** risks.

7.15 The risks to bystanders for most use patterns (17 scenarios) were considered **low** however these risks were still above the level of concern. Only one use pattern was considered to have **negligible** risks to bystanders.

7.16 No use pattern presented **negligible** risks to both operators and bystanders, such that **non-negligible** risks were present to 2 of 3 receptors for all use scenarios.

Environmental effects

7.17 The 2013 reassessment concluded that exposure of the environment to diazinon, fenamiphos and methamidophos would present **non-negligible** risks of significant adverse effects. We have highlighted key aspects of the risk assessment regarding adverse effects to the environment below.

7.18 We note that all use scenarios for diazinon, fenamiphos and methamidophos were modelled to have **negligible** risks to bees based on the assumption that users ensure bees will not be in the application area when the substance is applied in accordance with the controls applied to the substance.

Diazinon

7.19 Many use scenarios for diazinon were associated with **low** or **medium** risks to aquatic organisms (29 low and 34 medium scenarios).

7.20 The majority of uses carry **high** risks to birds (84 of 95 scenarios are **high** risk and 8 are **medium** risk). A significant number of the high-risk scenarios have RQ which exceed 1000.

7.21 It is notable that there is a very limited number of use patterns that present **non-negligible** risks to the environment, with most use patterns assessed presenting risks above the level of concern to at least one environmental receptor.

Fenamiphos

7.22 The use of the substance for biosecurity via dipping does not result in exposure to the environment and therefore presents **negligible** risks. This is the only use pattern which presents negligible risks to the environment, with all dispersive use patterns presenting risks to aquatic ecosystems or birds.

7.23 Fenamiphos was found to have **medium** to **high** environmental risks for most use patterns. Dispersive application methods were found to pose a **non-negligible** risk to the aquatic environment with four presenting a **medium** risk.

7.24 Five use patterns presented a **high** risk to birds with several exceeding RQ values of 2500. The other dispersive use pattern was considered to present **medium** risk. No dispersive use patterns presented **low or negligible** risks to birds.

Methamidophos

7.25 Similar levels of risks were associated with all use patterns for methamidophos.

7.26 All but one use pattern assessed for methamidophos found **medium** risks to the aquatic environment. Notably, high RQ values were associated with potential adverse effects to the

environment however qualitative risk assessments considered that these could be sufficiently mitigated with controls.

7.27 All use patterns were found to have **medium** risks to birds even with risk mitigating controls applied.

Current Reassessment

7.28 No new information has been provided by the applicant in relation to human health effects or risks associated with the use of diazinon, fenamiphos or methamidophos.

7.29 The applicant has not proposed a change of use or changes to the restriction which could result in a change in the risks associated with the use of these substances.

7.30 Several submitters in opposition to the application provided information regarding potential human health effects associated with exposure to diazinon, fenamiphos or methamidophos. Most of this information cited academic journal articles and academic studies, although references were provided to regulatory reviews by the European Food Safety Authority (EFSA) and by the International Agency for Research on Cancer (IARC).

7.31 We note that the European Chemicals Agency (ECHA) has adopted harmonised classifications for diazinon, fenamiphos and methamidophos. We noted that these are unchanged from those set in New Zealand following the previous reassessment. Similarly, we note that the US EPA has not adopted any updates to the classification of these active ingredients in the interim period between this application and the previous reassessment of these substances in New Zealand.

7.32 Furthermore, we note that the regulatory position of these agencies regarding diazinon, fenamiphos or methamidophos has not changed in the period following the 2013 reassessment. Any regulatory action which has occurred in the United States or the European Union following 2013 was either under implementation in 2013 or has taken effect because of decisions set prior to the 2013 risk assessment.

7.33 We have reviewed the journal articles cited by submitters regarding human health information and note that this information supports the conclusions of the previous risk assessment, namely that there are **non-negligible** risks associated with exposure to diazinon, fenamiphos and methamidophos. However, we do not consider the information supplied sufficient to warrant an update to the classifications for diazinon, fenamiphos or methamidophos.

7.34 We note the IARC decision to classify diazinon as a Group 2 probable carcinogen. However, we note that this has not been adopted to the EU harmonised classification nor adopted by the US EPA. We do not consider there to be sufficient information available to warrant adoption of the carcinogen classification for diazinon and a review of any associated risk.

7.35 In response to concern from Fish and Game regarding the effects on waterfowl. We highlight the previous risk assessment identified high risks to birds associated with the use of diazinon, particularly in association with broadcast use of the substance. We consider that the previous risk assessment addressed the risks associated with diazinon's activity as an acetyl

cholinesterase inhibitor, and that sufficient further information has not been identified to review this risk assessment and/or the controls applied to mitigate these risks.

7.36 As no risk assessment information has been supplied by the applicant, we consider that there is not sufficient information available to review the risk assessment applied to the previous reassessment. Furthermore, we consider that the information relating to risks and adverse effects supplied by the submitters opposing the application, support the original conclusions of the previous reassessment, namely that these substances pose a significant risk to users and the environment and should be subject to a phase out from use.

Summary of risk assessment

7.37 The previous reassessment found that, with additional controls applied, there are no use patterns for any of these substances which do not have any **non-negligible** risks to either human health or the environment.

7.38 Based on this risk assessment the EPA recommended that diazinon, fenamiphos and methamidophos all have their approvals declined. The EPA recognised the benefits associated with these substances and proposed phase out times which balanced the risks and benefits of the continued use of these substances.

7.39 No changes to the use of these substances have been identified in the applicant's information, nor the submission documents. No new risk assessment information has been supplied in the application nor in any material submitted to the EPA during the course of the current reassessment.

7.40 Therefore, the risks to human health and to the environment associated with the use of diazinon, fenamiphos, and methamidophos are considered to remain **non-negligible**. We do not consider that there is a change in the level of risk associated with the use of the substances to merit a change in the phase out period for these approvals.

8 Effect on society, the community, and the market economy

8.1 In the 2013 reassessment, the EPA considered that there were both adverse effects and benefits to society and communities. These adverse effects and benefits were not quantified. The adverse effects related to anxiety and social concern regarding exposure and harm to non-target species and bystanders, while the benefits assessment considered the future capability to counter pest problems and the downstream effects on industry users and communities associated with the loss of organophosphates and carbamates. Similar concerns have been expressed by the applicant and submitters who opposed the current reassessment application.

8.2 The applicant has indicated that they consider that there would be a significant impact on the economy of New Zealand, for those growers they claim are reliant on the use of diazinon, fenamiphos and methamidophos, if the approvals for these substances are not extended. These are discussed further in the benefit and cost assessment sections (see section 11 and 12 respectively).

8.3 In their submissions, Federated farmers and Nufarm state that they consider that the absence of diazinon for the control of grass grub will have significant effects on the arable sector as well as downstream effects on other sectors which rely on the arable production such as the meat and dairy industries.

8.4 In their submission opposing the application, the Environmental Law Initiative ("ELI") indicated concerns regarding the long-term impacts to communities as a result of the human health effects arising from exposure to diazinon, fenamiphos or methamidophos, in particular, they highlighted the costs of long-term disease burdens arising from exposure to organophosphates. This is discussed further in section 12.

9 Māori assessment

9.1 Prior to lodging their application, the applicant circulated a summary of their proposal including their application form to the Te Herenga network via the EPA Kaupapa Kura Taiao team. They requested feedback between 23 December 2020 until 12 February 2021.

9.2 No response to the applicant's proposal was received at this time, and the applicant did not proceed with further engagement with Māori.

9.3 In their application the applicant states that they received no objection or additional information from the circulation of their application material with Te Herenga. They have not provided any other assessment of the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to Sections 5(b), 6(d) and 8 of the HSNO Act.

9.4 In response to a request for further information made by the EPA under Section 52 of the Act, the applicant stated that they consider that the application, if successful, would result in a continuation of the risks and benefits to Māori as assessed in the 2013 reassessment as no change was proposed to the use patterns associated with these substances. As no response was received during their consultation via Te Herenga, they considered that there was no interest from Māori and further engagement was not necessary.

9.5 The Kaupapa Kura Taiao team has undertaken a Māori impact assessment of the proposal. The assessment found ongoing benefits and risks associated with the continued use of the substance, noting the concerns raised by submitters regarding potential risks to birds and to human health. The Māori impact assessment is provided in a standalone report available in the application register on the EPA website.

9.6 Overall, the assessment concluded that the benefits associated with diazinon, fenamiphos and methamidophos to Māori were unlikely to outweigh the detrimental impacts to Māori. While it was considered that the current controls were sufficient to mitigated impacts to cultural receptors over the current approval timeframe, the substances should still be phased out. The impact assessment concluded that there was not sufficient new information to justify an extension to the phase out periods.

10 Alternatives

10.1 Critical to the application is the proposal that there are no alternative substances which will be available to control critical pest species across various crop scenarios when diazinon, fenamiphos or methamidophos cease to be approved.

10.2 In table 6 of their application, the applicant has identified use patterns for which they state the use of diazinon, fenamiphos and/or methamidophos are required for growers to sufficiently control pest specifies. The application form does not however indicate which use patterns have no alternative pest control methods and which use patterns they consider the alternatives available to be insufficiently effective for control of specific pest species.

10.3 The application also lists several chemistries which have been approved in New Zealand following the 2013 reassessment. It goes on to assess viability of these substances as replacements for the critical use patterns they identify for diazinon, fenamiphos or methamidophos. They state that there has been limited development of new substances which can replace the use of diazinon, fenamiphos or methamidophos.

Alternatives to diazinon and methamidophos

10.4 While not an exhaustive list, the Novachem New Zealand Agrichemical Manual lists substances which have registered label claims for various pest and plant protection uses. The current manual lists alternative substances with label claims for most pest species where diazinon or methamidophos are identified as critical for the control of.

10.5 We have not undertaken an assessment of these alternatives regarding their efficacy, economic viability or any limiting factors which may influence their viability as replacements for diazinon or methamidophos, rather we note these label claims regarding the applicant's statement that there are no alternative substances to diazinon, fenamiphos or methamidophos for these use patterns.

10.6 Of the pest species which the applicant claims as there being no alternative substances for control of (table 6 of the application), the only pests which do not have any alternative substances with label claims against are carrot rust fly, and green vegetable bug.

10.7 While only methamidophos substances held claims against 'Tuber moth', a variety of substances hold label claims for potato tuber moth. Similarly, no claims (including methamidophos) were identified against fruit worm however several different substances list claims for control of tomato fruit worm.

10.8 Lucerne flea, army worm and weevils have alternative substances available, however these appear to be limited in diversity of chemical functionality and/or for each critical use pattern.

10.9 The remaining critical pests listed in table 6 of the application appear to have multiple different substances with label claims against them, across various growing scenarios. For most pest control scenarios listed, there are multiple different chemical functionalities including

pyrethroids, neonicotinoids, macrocyclic lactones (Spinosad and spinetoram), keto-enol (Spirotetramat), and Pymetrozine (pyridine azomethines) as well as organophosphates and carbamates which retained their approvals following the 2013 reassessment. For these use patterns, the absence of diazinon or methamidophos is unlikely to lead to reliance on a single mode of action.

10.10 In addition to chemical control agents, there are several biocontrol agents which have label claims for the control against several of the applicant's critical pest/ crop scenarios.

Alternatives to diazinon for grass grub control

10.11 The applicant has identified the control of grass grub in pasture and arable scenarios and in multiple submissions as a pest species for which retaining diazinon approvals is considered particularly critical. We note chlorpyrifos and the biocontrol agent *Serratia entomophila* hold label claims for use on pasture, while there are multiple pyrethroids and organophosphates with use patterns for grass grub on other crop scenarios.

10.12 In their submission, Federated Farmers claim that diazinon is the only substance for post planting control of grass grub larvae in arable crops. However of the control agents, there does not appear to be any diazinon substances with label claims against grass grub larvae.

Fenamiphos

10.13 The treatment of nematodes is identified by the applicant and submitters in support of the application as a use pattern as a key use for which there is not an adequate replacement. We note that the applicant has identified fluopyram as being listed for the suppression of nematodes, while the Novachem New Zealand Agrichemical Manual also identifies *Bacillus firmus* as a biocontrol agent for suppression.

10.14 We also note that there is currently an application for a release approval of Nemitz, a nematicide which contains a new active ingredient fluensulfone (APP204035). The application for a release approval of Nemitz is a separate and ongoing process to this reassessment, and therefore should not be relied upon when considering the approval timelines for fenamiphos. While not currently approved and therefore available as an alternative for fenamiphos, the application indicates that there are alternative substances in development which may replace the use of fenamiphos in the near future.

11 Benefit assessment

11.1 Diazinon, fenamiphos and methamidophos are used as insecticides for crop protection purposes, and therefore the primary benefit for these substances relates to the production from these crops. The applicant has, however, noted that there are also biosecurity uses associated with these substances.

11.2 The applicant has identified crops and use patterns for which the substances are deemed to be critical, because they state that there are limited or no alternative substances which can replace their use.

Benefits assessment supplied by the applicant.

11.3 In their application form, the Vegetable Research Board ("the applicant") state that industries which rely on one or more of diazinon, fenamiphos and/or methamidophos provide a combined value of $1.75 billion annually and provide employment to approximately 23,000 New Zealanders. They highlight that the industries which use these substances are predominantly based in rural areas.

11.4 The application provides a breakdown of the contributions of different industries to these figures; however, it does not provide information to distinguish the specific economic benefits provided by diazinon, fenamiphos or methamidophos. Similarly, submitters provided information regarding the value of their industry but did not provide a breakdown of the economic contribution provided by the use of these substances.

11.5 In an information request under Section 52 of the Act the EPA requested a further detailed economics assessment specific contribution of the different substances to the GDP generated by the production of the crops on which they are used and information on the predicted impact on GDP of these substances becoming unavailable. The applicant did not provide this information in their response.

11.6 In their response to an information request the applicant reaffirmed that they are seeking to largely apply the benefits assessment as undertaken in the 2013 reassessment, but with a reconsideration of the relative weighting of this benefit with the context that there has been limited development of substances to replace diazinon, fenamiphos and methamidophos in the interim period.

11.7 The applicant has not provided updated figures which could be applied to update the benefits assessment, to account for changing cost and values in the relative markets to which the use patterns for these substances provide benefit.

11.8 As noted in section 10 of this report, there are multiple substances which appear to have label claims against the critical use patterns identified by the applicant such that they could be considered alternatives to diazinon or methamidophos. No information has been provided by the applicant or submitters to illustrate the economic benefits associated with diazinon or methamidophos when compared to these alternatives.

11.9 Additionally, there is limited discussion regarding benefits such as efficacy, reduction of resistance, use pattern or any quantitative benefit information for diazinon, fenamiphos and methamidophos when compared to the benefits of any potential alternatives.

11.10 Therefore, we consider there is insufficient new information to determine that there is an increase in economic benefits associated with the applicant's proposal.

Benefits to human health and the environment

11.11 The applicant has sited that the use of the substance for biosecurity measures will provide benefit to the environment through the prevention of the incursion of biosecurity pests which may impact New Zealand ecosystems and/or human health as disease vectors.

11.12 The applicant has not however provided any quantitative information regarding this use pattern nor the costs or impacts on the withdrawal of these substances for this use. No other benefit to human health or the environment is cited by the applicant or any submitters in support of the application.

11.13 In their submission Ministry for Primary Industries (MPI) discussed the use of fenamiphos and methamidophos for biosecurity. MPI outlined that while fenamiphos is used at low volumes in a biosecurity setting, the commodities which require treatment are high risk. Furthermore, they state the search for alternatives is an active area of research and that there are currently no alternatives listed as approved treatments on the MPI-ABTRT. MPI therefore considers there to be high biosecurity value to extending the approval time for fenamiphos.

11.14 We note that MPI has not provided a quantitative estimate of the benefits to New Zealand through biosecurity use. However, as the competent authority for biosecurity in New Zealand we accept the qualitative benefit information provided in their submission, and therefore consider that the protection of high-risk imports is likely to provide significant **non-negligible** benefits to New Zealand. Based on the information provided by MPI we consider biosecurity use provides **medium** benefit.

11.15 In addressing the use of methamidophos, MPI notes that the treatment protocol which can include the use of methamidophos is rarely directed, and when it is used, methamidophos is rarely selected as the treatment substance, with alternative substances preferable. They also highlighted the high risks to operators associated with this substance. They consider that extended use of methamidophos is therefore less critical than that of fenamiphos.

11.16 Based on the information provided by MPI we consider that the benefits associated with the continued use of methamidophos for biosecurity use a **negligible** to **low** and unlikely to outweigh the risks associated with the substance.

11.17 MPI did not provide any information regarding the use of diazinon in biosecurity, except to note that the applicants proposed use of diazinon and/or methamidophos as a treatment for brown marmorated stinkbug was unlikely due to the risks these substances pose to operators and bystanders and that they do not currently list these as substances for the control of an incursion.

11.18 We note the previous risk assessment included modelling for a biosecurity use pattern for diazinon. As MPI notes that diazinon is not an approved treatment option in the MPI-ABTRT and no information was provided regarding biosecurity use we consider that diazinon is no longer used for biosecurity and therefore there is no benefit associated with this use pattern.

11.19 Based on the information provided by the applicant and MPI we consider that fenamiphos is the only active ingredient subject to this reassessment for which there is new information to illustrate significant benefit to human health and the environment to support extension of its approval.

Overall benefits assessment.

11.20 There is not sufficient information to quantify the benefits provided directly by the use of diazinon, fenamiphos or methamidophos continuing to be used over the proposed extension timeframe or quantify the impacts to benefits these substances provides should transition to an alternative substance occur.

11.21 Therefore, we consider that it has not been demonstrated that there is an increase in the benefits associated with the applicant's proposal.

11.22 We consider the use of fenamiphos for biosecurity to be an exception to this assessment. There are also likely to be ongoing benefits to the economy, human health, and the environment from the use of fenamiphos in biosecurity applications. We consider there to be **medium** benefits to retaining fenamiphos for this use only.

12 Cost assessment

Costs associated with substances diazinon, fenamiphos and methamidophos becoming unavailable

12.1 The applicant considers that there will be significant economic impacts to industries where the substances are considered critical for crop protection should these substances become unavailable. They also consider there to be economic costs associated with transition to alternative substances.

12.2 The applicant has identified critical use patterns for which they state the use of diazinon fenamiphos and/or methamidophos are required for growers to sufficiently control pest specifies. This information is detailed in table 6 of the application form. They consider that there will be significant costs associated with diazinon, fenamiphos or methamidophos no longer being available for these uses.

12.3 The applicant has not put forward any monetised costs associated with fenamiphos or methamidophos becoming unavailable in 2023 and diazinon becoming unavailable in 2028. No cost information has been provided regarding the direct losses associated with these substances becoming unavailable, the cost to alter pest control practices or transition to other substances.

12.4 In their submission, Nufarm Limited cites information from The Foundation for Arable Research which attributes an approximate cost of $32 million arising from 10% loss of yields to farm returns resulting from reduced control of grass grub. They do not state whether this value is a representative figure regarding the impacts of grass grub to yields, or whether this impact on yield attributed to the use of diazinon.

12.5 It is not apparent from the information provided in the application or the submission nor any other information provided as to the impact on yield which could be attributed to diazinon or alternative methods of grass grub control.

12.6 In their submission, Federated Farmers state that diazinon is the only agrichemical control currently available for grass grub in arable crops. They state that grass grub impacts pasture for livestock and arable crop industries, which have significant value to New Zealand. While they provide figures for the value provided by the arable crop and livestock industries as a whole, they do not provide quantifiable information as to the level of the impact of grass grub when not controlled by diazinon, or the comparable impact if alternative control measures were used.

Costs associated with extended approval of diazinon, fenamiphos and methamidophos

12.7 There are likely to be costs arising from the proposed extension to the approval of diazinon, fenamiphos and methamidophos when compared to the current expiry of the approvals. Any costs would relate to ongoing exposure to the substances and the associated risks of adverse effects on human health and the environment (see the risk assessment, section 7). The

applicant has not provided an estimate of the costs associated with an extension of 10 years to the current phase out dates.

12.8 In their submission, ELI noted an estimated annual cost from human health effects associated with exposure to organophosphates (see section 4, submissions in opposition). We have not validated these cost impacts but note the claims are significant. However, we note it is not clear what contribution is sourced from diazinon, fenamiphos or methamidophos. Furthermore, these costs are associated with potential intelligence quotient (IQ) impacts from endocrine disruption, an effect which has not been validated in New Zealand or in the European Union for diazinon, fenamiphos and methamidophos. These figures may also be influenced by other factors. Therefore, it is not apparent as to how these figures would translate to a New Zealand context.

Summary of cost assessment

12.9 Based on the information provided we are unable to make a quantifiable assessment of the costs associated with diazinon, fenamiphos or methamidophos approvals being revoked in 2028 and 2023 respectively, nor a comparative assessment of the costs associated with adverse effects from exposure to these substances should the approvals be extended a further 10 years.

13 Controls

13.1 The EPA has reviewed the information made available by the applicant and submitters, both in support of the application and in opposition.

13.2 No change to the controls has been proposed by the applicant nor submitters in support of the application. Similarly, no change in the use patterns associated with these substances which would require a change to the controls has been proposed. Therefore, no changes are proposed by the applicant to reduce the risks associated with the substance.

13.3 Submitters in opposition have indicated they consider additional controls should be applied to further restrict the substances over their phase out periods, however they have not proposed any specific controls.

13.4 We note the submission from Fish and Game New Zealand seeks greater restrictions to prevent risks to waterfowl and suggests more adaptive measures which are tailored to climate and/or local conditions. Under the Act, controls adaptive to local or changing conditions could only readily be achieved through the implementation of a control requiring the granting of permission for use by the authority under Section 95A of the Act.

13.5 We do not consider that a permission requirement would be appropriate for any dispersive use patterns associated with these substances as plant protection products. We consider that it would be difficult to obtain sufficient information to inform an assessment of site-specific conditions associated with the dispersive uses of diazinon. The application of a permissions scheme for a substance which has widespread use would likely be costly, as well as regulatorily and administratively burdensome. Furthermore, we do not consider there to be sufficient evidence to illustrate a significant benefit to justify a permissions control. Therefore, we consider costs would likely exceed the benefits associated with a permissions control.

13.6 In summary we do not consider that there is sufficient information provided to illustrate any necessary changes to the controls associated with the use of diazinon and methamidophos or the use of fenamiphos outside of biosecurity use. We therefore propose that the controls as set in the 2013 reassessment APP201045 are retained.

Ongoing use of fenamiphos for biosecurity use only

13.7 As noted in the risk and benefits assessments (sections 7 and 11 respectively) the use of fenamiphos for biosecurity purposes is associated with a lower risk and **non-negligible** benefit associated relative to other fenamiphos use patterns. As such, we consider that there may be sufficient benefit to permit the extended approval of the use of fenamiphos beyond the current phase out in 2023.

13.8 Should the DMC approve the ongoing approval of fenamiphos for biosecurity uses only, a use pattern restriction control under Section 77A of the Act should be applied to limit the use of fenamiphos to biosecurity uses and competent agencies as defined in the Biosecurity Act 1993. We would recommend the following control for this purpose:

(1) From 01 June 2023 no person can apply the substance except for biosecurity purposes;
(2) Biosecurity purposes in (1) means use for operations carried out under the Biosecurity Act 1993.

13.9 If the DMC were to seek additional restriction to biosecurity uses such as adaptive site by site controls, or ongoing justification of the benefits of each biosecurity use of fenamiphos, this could be achieved through the use of Section 77A(2) of the Act to obligate users of fenamiphos to obtain a permission for its use:
(1) No person may apply fenamiphos for biosecurity purposes unless that person first obtains a permission from the Authority under Section 95A of the Hazardous Substances and New Organisms Act 1996.
(2) Biosecurity purposes in (1) means use for operations carried out under the Biosecurity Act 1993.

13.10 A permission control would allow for extended use of fenamiphos for biosecurity, where permission applicants are able to justify the use of fenamiphos, for example the absence of an alternative substance for specific biosecurity treatment, and to illustrate the risk mitigation measures proposed to mitigate continued use at their specific biosecurity site. A similar permissions requirement has been applied under the Firefighting Chemicals Group Standard to permit the use of C6 firefighting foams beyond the phase out date in 2025.

14 Overall evaluation and recommendation

14.1 We have reviewed the information which has been made available in relation to the modified reassessment application to assess the applicant's proposal and the possible changes allowed for under the reassessment scope.

14.2 We do not consider that the applicant has provided sufficient evidence or justification to illustrate that the risks associated with the use of diazinon, fenamiphos or methamidophos have changed either through evidence of lower risks of adverse effects associated with these substances or through proposed changes to the use pattern and/or controls which would reduce exposure to these substances resulting in a reduction of risk.

14.3 We do not consider that sufficient evidence of an increase in benefit associated with the use of the substance has been illustrated by the applicant or any submitters in support of the application. We therefore consider that the benefits remain in line with those assessed in the previous reassessment.

14.4 While the scope allows for the date that the approvals expire to be shortened or for additional restrictions to be applied over the remainder of the approval timeframe, we do not consider that there is sufficient evidence for the EPA to do so. We consider that the information provided by submitters who oppose the reassessment application, supports the conclusions of the original risk assessment.

14.5 As there is no new evidence to illustrate a change in the risks or benefits associated with the use of the diazinon, fenamiphos and methamidophos, we consider that the balance of risks and benefits as considered in the previous reassessment remains unchanged.

14.6 The use of fenamiphos as a biosecurity treatment is considered an exception to the assessment. We consider that there are lower risks for this use pattern and note there are no other substances approved under MPI's Treatment Requirement (MPI-ABTRT) protocol, such that there is a **non-negligible** benefit associated with this limited and restricted use. We therefore propose that the DMC consider a limited extension to the approval of fenamiphos for this use only.

14.7 In summary we consider that there is not sufficient new information to illustrate that the benefits associated with the applicant's proposal outweigh the risks of the extended use of these substances. We recommend that the application is declined and that the approvals for diazinon and methamidophos remain unchanged. For fenamiphos we recommend that the application is declined for all use patterns except for biosecurity use by approved agencies.

Consideration of Matters in Part 2 of the Act

14.8 The purpose of the Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

14.9 All persons exercising functions, powers and duties under the Act shall recognise and provide for the principles set out in Part 2, Section 4 of the Act and take into account matters specified in Part 2, Sections 6 to 8 of the Act.

14.10 In respect of Part 2, the EPA staff have given consideration to all Part 2 matters as part of this staff report, including consideration of impacts on Māori (see the associated Māori Impact Assessment report).

14.11 The application has been publicly notified such that persons who may be affected by the outcome of the reassessment have either been consulted with and/or had an opportunity to engage in the application process.

14.12 Given the matters set out above, we consider sufficient consideration of the Part 2 matters has been undertaken in this report in order to achieve the purpose of the Act when providing an assessment to the DMC on the application for a modified reassessment of diazinon, fenamiphos and methamidophos.

Appendix A: Approvals subject to reassessment

Active ingredient	HSNO Approval Number	Trade name
Diazinon	HSR101016	Dianex Diazate
	HSR000180	Dew 600 Diazol Insecticide Zagro Diazinon 600EW
	HSR000181	Digrub
	HSR000175	Gesapon 20G Diazinon 20G
	HSR002481	Diazol 800
	HSR000174 HSR000176 HSR000177 HSR000178 HSR000179 HSR000182 HSR000183 HSR000184 HSR007700 HSR100760 HSR100878	No trade name products identified
Fenamiphos	HSR000956	Nemacur Fenafos 400
	HSR007769	Nematak 400EC
	HSR100282	Canyon
	HSR000198 HSR002480 HSR007894	No registered trade name products identified
Methamidophos	HSR000226	Metafort 60SL Methafos 600
	HSR002863	*Methamidophos active ingredient*
	HSR000203	No registered trade name products identified

Appendix B Recommended new controls

Proposed new controls for fenamiphos approvals

Use pattern Restriction: Biosecurity use

(1) From 01 June 2023 no person can apply the substance except for biosecurity purposes;
(2) Biosecurity purposes in (1) means use for operations carried out under the Biosecurity Act 1993.

Requirement to obtain permission from the Authority for Biosecurity use

(1) No person may apply fenamiphos for biosecurity purposes unless that person first obtains a permission from the Authority under Section 95A of the Hazardous Substances and New Organisms Act 1996.
(2) Biosecurity purposes in (1) means use for operations carried out under the Biosecurity Act 1993.

Appendix C Submitters details

Table Submitters' details

Submission number	Submitter name	Submitter organisation	Abbreviated Submission name
SUBMISSION127696	Dave Nendick	Ministry for Primary Industries - Wellington (Head Office)	MPI
SUBMISSION127697	Stephanie Dijkstra	Te Rūnanga o Ngāi Tahu	Ngai Tahu
SUBMISSION127706	Rebecca Reed	Fish and Game Council of New Zealand	Fish and Game
SUBMISSION127707	Jodie Bruning	Physicians and Scientists for Global Responsibility (PSGR)	PSGR
SUBMISSION127723	Jodie Bruning	The Soil & Health Association of New Zealand Inc	Soil and Health
SUBMISSION127724	Caroline Cooper-Dixon	Akaroa Rona's Ltd	*Not abbreviated in the report.*
SUBMISSION127725	Claire Bleakley	GE Free Northland (in Food and Environment)	GE Free
SUBMISSION127726	Matthew Hall	Environmental Law Initiative	ELI
SUBMISSION127727	Meenu Matharu	Nufarm Limited	Nufarm
SUBMISSION127728	John Hicking	Orion AgriScience Limited	*Not abbreviated in the report.*
SUBMISSION127729	Andrew Thompson	Agrisource (2000) Limited	Agrisource

Disclaimer

Further information

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