



Environmental
Protection Authority
Te Mana Rauhi Taiao

EVALUATION AND REVIEW REPORT

APP202142 – Modified reassessment of certain organophosphate and carbamate plant protection insecticides

February 2015



Executive Summary

This Evaluation and Review report incorporates information received from submissions on the modified reassessment of certain OPC substances, and should be read in conjunction with the two accompanying appendices and the original application.

The EPA would like to thank all the people who responded to our requests for information and provided submissions. The time and effort you have spent has been a valuable contribution to the evaluation process.

The purpose of this application is to determine whether the post-application risks to bees of exposure to certain organophosphate or carbamate insecticides are adequately managed, and to determine whether restrictions, specifically non-contact periods, are appropriate.

Grounds to undertake this reassessment were established after the EPA's recent group reassessment of organophosphate and carbamate plant protection products, on the basis that significant information was not taken into account when deciding the group reassessment.

In the current application, the EPA staff assessed the new information and proposed that there were post-application risks to bees that were not managed by the controls determined in the group reassessment. Accordingly, the staff proposed restrictions for plant protection substances containing acephate, dimethoate, methamidophos, methomyl or oxamyl.

Submissions have been received on these proposals and the EPA staff have updated the proposals, with **amendments highlighted**, as shown in Table 1.

Table 1: Updated recommendations for substances included in the Application

Active ingredient	Recommendations
Acephate	<ul style="list-style-type: none"> Implement non-contact period of 7 days Require label statement detailing the non-contact period
Dimethoate	<ul style="list-style-type: none"> Implement non-contact period of 7 days Require label statement detailing the non-contact period
Methamidophos	<ul style="list-style-type: none"> No non-contact period required - application restricted to evening time Require label statement detailing the application restriction
Methomyl	<ul style="list-style-type: none"> Implement non-contact period of 8 days Require label statement detailing the non-contact period
Oxamyl	<ul style="list-style-type: none"> Implement non-contact period of 10 days Require label statement detailing the non-contact period

Overview of the EPA-initiated Reassessment process

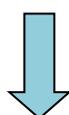
Grounds Application

Grounds must be established in order for an application for a reassessment to be lodged. An application for grounds is lodged with the EPA and is heard by an independent decision making committee established under HSNO.



Reassessment Application

Once grounds have been established, an application for a reassessment is lodged and notified for public consultation. The application contains the staff's initial assessment, including draft recommendations for the decision making committee



Evaluation and Review Report

After receipt of submissions on the proposals in the application, EPA Staff prepare an evaluation and review report taking into account information that has been submitted. This will be considered by the decision making committee.

This document is the Evaluation and Review Report.



Public hearing and consideration

A public hearing will be held, and once the decision making committee is satisfied that they have sufficient information to make a decision, the application will be considered.



Decision

After a public hearing and consideration of the application, the decision making committee will issue its final decision.

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1. Background

The EPA recently completed its reassessment of organophosphate and carbamate plant protection products (APP201045). In its assessment, it was considered that the risks to bees arose as a consequence of direct exposure to pesticide spray solution rather than through contact with residues of dried chemical well after application.

Accordingly, the decisions made during that reassessment did not re-impose non-contact periods on any of the substances reassessed.

Information was subsequently provided to the EPA by the National Beekeepers Association (NBA), who were concerned that dimethoate-containing substances could pose risks to bees for a significant period of time after application. A decision making committee of the EPA subsequently decided that there were grounds to reassess plant protection substances containing acephate, dimethoate, methamidophos, methomyl or oxamyl), under section 62 of the Hazardous Substance and New Organisms (HSNO) Act.

Following on from the establishment of grounds, the Chief Executive of the EPA applied for a modified reassessment to review whether use of these substances should be subject to non-contact periods in order to protect bees from post-application exposure. EPA staff (“the staff”) assessed the available data for the five active ingredients in question and made initial recommendations in the Application. The staff recommended that restrictions be imposed on all of the substances covered by this application.

Submissions on the Application were received by the EPA.

This Evaluation and Review report includes the staff’s responses to key points raised in the submissions, and the staff’s updated proposals after taking into account the submissions received.

This report contains:

- a summary of the submissions and key issues raised in response to the initial proposals outlined in the Application and
- updated recommendations to modify the approvals.

2. Summary of submissions

This section highlights the key issues and points relevant to the scope of this application raised by the submitters. For ease of evaluation, these issues have been broadly grouped by topic. The complete submissions can be found on the EPA website.¹ This section also highlights where the submissions have resulted in the staff revisiting their original recommendations. These are noted here and

¹ <http://www.epa.govt.nz/search-databases/Pages/applications-details.aspx?applID=APP202142#>

included in the recommendations section. The final, updated staff recommendations are presented in section 3 of this report.

Table 2: Summary of submissions received

No. of submissions received	17
No. of submissions supporting application proposals	9
No. of submissions opposing application proposals	3
No. of submissions not indicating support or opposition to application proposals	5
No. of submitters wishing to be heard	9

Submissions were received from the individuals or organisations detailed in Table 3.

Table 3: Details of submissions

Submission Number	Submitter	Submitter Organisation (if relevant)
110264	Frank Visser	Key Industries Limited
110567	Yvonne Curtis	
110579	John Liddle	Nursery and Garden Industry Association of New Zealand Inc
110606	Timothy Wilson	Arysta LifeScience North America Corporation
110612	James Hadlow	Stepping Stones Nursery Limited
110613	Oliver Sutherland	Te Rūnanga o Ngāi Tahu
110614	Noel Blackwell	Rural Contractors New Zealand
110615	Ann Thompson	Federated Farmers of New Zealand (Incorporated)
110616	Lorraine Anderson	Ngāti Huarere Ki Whangapoua Trust
110617	Paul Havemann	
110618	Joan Havemann	
110619	Don MacLeod	National Beekeepers Association of New Zealand
110620	Malibu Hamilton	Clean Earth
110621	Rebecca Fisher	Market Access Solutionz Ltd
110622	Greg Mitchell	DuPont (New Zealand) Limited
110623	Vera van der Voorden	
110624	Nora van der Voorden	

2.1. Availability of alternatives

The submissions have been reviewed and the key points raised are detailed below, along with the staff's responses.

Submission number	Submitter comment	Staff response
110579	The submitter cautions against removal of chemical tools from the 'toolbox' until alternatives with demonstrated efficacy are available.	The staff note that, when substances are approved, risks and benefits are assessed. The benefits assessment takes into account the availability of alternative options. The staff note that the purpose of this application is to determine whether a modification to a control is required in order to adequately protect bees is required. The staff have not proposed to remove the approvals for any of the affected substances in this application.
110617	The submitter considers that organic practices should be promoted by the government.	The staff note that consideration of alternative growing practices is outside the scope of this application.
110618	The submitter highlights the need to consider alternative growing practices, such as organic production, when evaluating substances.	The staff note that, when substances are approved, risks and benefits are assessed. The benefits assessment takes into account the availability of alternatives, which includes alternative production methods. However, the HSNO Act allows a substance to be approved when the benefits associated with availability of the substance outweigh the risks of use of the substance, considering what control measures can practically be implemented to mitigate the risks.

Impact on staff proposals:

The staff do not consider that any of these issues necessitate changes to the staff proposals regarding the implementation of the proposed non-contact periods.

2.2. Awareness and compliance

Submission number	Submitter comment	Staff response
110615	The submitter highlights the need for clear labelling statements in order to ensure that users are aware of the non-contact periods that apply.	The staff agree that any non-contact periods that are imposed need to be reflected on the product label so that users are aware of their obligations. This, in

Submission number	Submitter comment	Staff response
		<p>conjunction with the requirement to be an approved handler² when applying these substances, should ensure that the applicator is aware of the requirements of any non-contact periods that are relevant for a given substance. Accordingly, the staff proposals have been amended to require non-contact periods to be explicitly stated on product labels.</p>
110619	<p>The submitter suggests that highlighting non-contact periods may make applicators aware of the nature of the substances that they are using (i.e. that these substances have residual toxicity to bees), and may be a factor in deciding to use alternative products as a result.</p>	<p>The staff note that awareness of controls and use restrictions is critical for the controls to achieve their intended risk management outcomes. In order to handle these substances, a person must be an approved handler, which requires that person to know the controls that apply to the substance. Furthermore, it would be beneficial for information, such as non-contact periods, to be specified on the product label. The staff's proposals have been updated to include the non-contact period on the product label.</p>
110619	<p>The submitter highlights concerns regarding the status of recently approved labels through the ACVM registration, not including reference to non-contact periods on their labels.</p>	<p>The staff consider that the outcome of this application will provide clarity and a definitive timeframe for implementation of non-contact periods. Going forward, importers and manufacturers will need to ensure that product labels do not misrepresent the requirements of the HSNO controls.</p>
110620	<p>The submitter indicates that self-monitoring of adherence to non-contact periods by growers/applicators should be replaced by a mandatory monitoring requirement.</p>	<p>The staff consider that an applicator would need to be able to demonstrate compliance with all of the controls that apply to a hazardous substance if an enforcement officer were to request it.</p>
110621	<p>The submitter considers that although non-contact periods were in place prior to the decision on APP201045, growers were poorly informed and were not aware of these requirements. This is why growers did not adhere to non-</p>	<p>The staff note that the ACVM-approved label for the acephate products Orthene and Lancer, prior to the decision on APP201045, included statements highlighting the non-contact periods to be followed. The staff consider that users and</p>

² A person who is in possession of a valid Approved Handler Test Certificate, in accordance with Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001.

Submission number	Submitter comment	Staff response
	contact periods previously.	applicators should be familiar with the label content of the products that they are using. Furthermore, it is the responsibility of the applicator to adhere to the controls and restrictions that apply to a hazardous substance. Accordingly, users should have previously been adhering to non-contact periods.
110623	The submitter considers that the measures proposed in this application do not go far enough in terms of protecting bees and pollinators, and should be subject to more severe restrictions. The submitter considers that application of these and other hazardous substances are not in accordance with the controls of the substance approval. The submitter does not consider the proposals in the application to be adequate and considers that additional steps need to be taken to ensure that these controls can be enforced to ensure bee protection. The proposals do not account for improper use or disregard of the legal controls that apply to these substances.	The staff note the submitter's comments. The staff consider that the proposed measures will be sufficient to manage the risks to bees. Furthermore, revocation of the approval is outside the scope of this application as a modified reassessment. Compliance with controls is not only an enforcement matter, but also a matter of education and communication. The restrictions imposed on these substances in the decision on the reassessment application APP201045 mean that application must be undertaken under the control of an Approved Handler, which requires knowledge of the conditions of use and the qualification must be regularly renewed. The EPA encourages reporting of incidents of non-compliance to allow enforcement officers to investigate and take appropriate action.
110623	The submitter proposes bee population monitoring and the implementation of a long-term strategy to improve bee health.	The staff consider that implementation of a monitoring programme is beyond the scope of this modified reassessment application, which can only review and amend conditions on existing approvals, specifically the implementation of non-contact periods.
110624	The submitter proposes that educational programmes to communicate the issues associated with bee health are implemented.	The staff note the submitter's comments and agree that education of users is critical to ensuring responsible and compliant use of these products. The staff note that the scope of this application is limited to the determination of non-contact periods for these substances. Guidance material issued as a result of the OPC reassessment (APP201045) can be updated to reflect the outcomes of this application, if required.

Submission number	Submitter comment	Staff response
	<i>Impact on staff proposals:</i>	
	<p>The staff consider that the non-contact periods/restrictions, if adopted, should be expressly detailed on the product labels. Accordingly, the staff propose to modify “Control/Label statement R-9: Label warning of effects on bees” for each of the affected substances. The updated control is presented in section 3.</p>	

2.3. Data and risk assessment

Submission number	Submitter comment	Staff response
110606	The submitter undertook a field study investigating the effects of acephate on bees. The study report has been provided to the EPA for consideration as part of this modified reassessment application.	The EPA staff have reviewed the study provided by the submitting organisation, concluding that the new study does not provide conclusive information that can be used to modify the staff's initial proposals for non-contact periods for acephate. Further details on the staff's review can be found in Section 4 of the document E&R Appendix B (revised), pages 224 to 227. ³
110621	The submitter considers that the staff's risk assessment overestimates the level of risk, noting in particular that in real-world scenarios other sources of nectar are available, other than treated flowers.	<p>The staff consider that this assumption is only partly valid because honeybee colonies can be used for pollination services, which is a very similar situation to the conditions of some of the field tests available for this assessment. However, although some field studies can be performed under “real-world” operational conditions, given that no such studies are available to the EPA at the present time, this assessment has been made using the best available information.</p> <p>Should such tests be conducted by industry in the future, the results of those tests could be used to undertake a review (i.e. a modified reassessment) of any non-contact periods established as a result of this application.</p>
110621	The submitter questions the difference between the assessment of risks to	The staff note that the assessment of APP201045 did not include the data and

³ <http://www.epa.govt.nz/search-databases/Pages/applications-details.aspx?applID=APP202142#>

Submission number	Submitter comment	Staff response
	<p>bees between APP201045 and in this application. Previously, risks to bees were identified as being a consequence of exposure arising from direct contact with pesticide spray.</p>	<p>information relied on to establish the grounds to undertake this reassessment. This information was determined to be new in the context of s62 of the HSNO Act, as it did not form part of the package of information presented to the decision makers on APP201045. Accordingly, grounds for a modified reassessment application were established. The staff consider that this new information materially changes the results of the risk assessment, identifying post-application exposure risks that require mitigation in order to adequately protect bees.</p>
110621	<p>The submitter notes that this application indicates that non-contact periods are not widely used by overseas regulatory authorities. Additionally, label statements, such as those provided for the methomyl product, Lannate L, are sufficient to protect bees:</p> <p><i>'Dangerous to bees. Do not spray any plants in flower while bees are foraging. Ensure beehives are removed from the area to be treated and from adjacent paddocks.'</i></p> <p>The submitter also details alternative protection measures that could be implemented to manage risks to commercial hives. Such measures include notification of beekeepers within a 2 km radius of application area in advance of spraying to allow the hives to be moved.</p>	<p>The staff consider that, while overseas regulatory bodies may not necessarily impose non-contact periods, some industry guidance materials⁴ do identify non-contact periods as a way to protect bees from exposure to pesticide sprays. The staff consider that there is a post-application exposure risk to bees that needs to be managed and considers non-contact periods as the best way to achieve the required level of protection. The quoted label statement does not provide sufficient protection to manage the post-application risks associated with these substances. The alternative provisions suggested are expected to only protect commercial hives and not offer any additional protection to wild and native bees, or other pollinators.</p>
110621	<p>The submitter considers that controls should be designed to manage risks to commercial honey bees because this is where the risks are greatest, rather than all kinds of bee (including wild and native bees).</p>	<p>The staff note that the greatest overall risks are presented to commercial honey bees, simply by virtue of the numbers of hives. However, the staff's proposals go further and will manage risks to other bees as well. While other measures could be implemented which specifically target the commercial hives, the staff consider that</p>

⁴ E.g. Hooven et al., 2013: How to Reduce Bee Poisoning from Pesticides, Oregon State University:

<http://ir.library.oregonstate.edu/xmlui/bitstream/handle/1957/42829/PNW%20591.pdf>

Submission number	Submitter comment	Staff response
		protection of other bees is also important and can be achieved through using non-contact periods.
110621	The submitter indicates that non-contact periods are not practical for continuously flowering crops, such as lemon trees. As a result, if non-contact periods are imposed, acephate would not be able to be used on lemon trees. The submitter notes that this would result in lemons not being grown, such is their dependence on acephate for lemon production.	The staff acknowledge the difficulty that non-contact periods present when considering continuously flowering crops. However, the staff note that this is not a new control and that protection of bees is essential. The staff accept that a consequence of this control may be to force growers to use other pest control measures that do not present post-application exposure risks to bees. The staff note that the non-contact periods are intended to restrict the use of products unsafe for bees. Where those risks are expected to be continuously present, such as in continuously flowering crops, it is intended that the substances are sufficiently restricted in order to remove those risks.
110621	The submitter questioned the relevance of data based on dislodgeable foliar residues, given that bees are not attracted to leaves and foliage. Furthermore, the submitter considers that the risks determined by the EPA have been overestimated.	Studies based on foliar dislodgeable residues are standard US EPA tests to evaluate the residual activity of pesticides on bees. They are low tier studies designed to identify issues. When issues are identified higher tiered studies more representative of the use conditions are requested. However, for some substances in this assessment no such higher tier study was available so the proposal is based on the lower tier studies, which, in the absence of data to refine the assessment, are necessarily conservative. If industry were able to provide higher tier data to refine the assessment, it may be possible to reduce the level of conservatism in the assessment.
110621	The submitter questioned the applicability of non-contact periods for indoor horticultural purposes, such as greenhouse crops.	The staff note that the wording of control E3 does not differentiate between indoor and outdoor use, and does not take into account the fact that bumble bees are commercially produced in order to pollinate greenhouse crops. It is anticipated that any effects on these bees are contained and that there would not be any effects outside of the greenhouse. It is our understanding

Submission number	Submitter comment	Staff response
		that, as far as possible, growers would try to avoid any effect on their bumblebees for the sake of their crop and due to the cost of using commercial bumblebee pollinator services. The proposed non-contact periods would help growers in this regard.
110621	The submitter considers that the overall effect on bee populations across New Zealand for lemons and strawberries will be minimal, on the basis that the land area for these crops represents a very small proportion of total New Zealand land area. This is significant because these growing sectors cannot live with non-contact periods for acephate and methomyl.	The staff do not consider it to be relevant to compare the whole land area of New Zealand with the surface area covered by strawberries and citrus, because these crops are localised in some regions where there are significant areas covered by these crops. In such areas, the impacts on bee populations is expected to be significant and require protection measures to be in place.
110621	The submitter notes the lack of references or evidence of actual adverse impacts associated with use of methomyl or acephate.	The evaluation is based on existing study data relating to the effects of methomyl from semi-field trials. A lack of reported incidents of adverse effects does not necessarily mean that safe use is being achieved; it is just as conceivable that incidents are not being reported or monitored. In the absence of monitoring data demonstrating safe use, the EPA relies on its risk assessment methodology in order to inform decision makers of risks associated with use of pesticides.
110622	The submitter has provided two studies to the EPA in confidence. The submitter estimates that the largest volume of Lannate L is used by the glasshouse industry, and exposure to honey bees outside of the glasshouses are expected to be minimal.	The staff note the submitters comments. Non-contact periods will still be required to manage risks posed as a result of outdoor use. The studies provided by the submitter have been evaluated by the staff. They were already part of the initial application because they were reviewed by EFSA ⁵ which considered that the results had to be taken with caution. The staff conclusion is the same: there are some deficiencies in these studies so the proposed non-contact

⁵ European Food Safety Authority

Submission number	Submitter comment	Staff response
		<p>period is not changed.</p> <p>Further details on the staff's review can be found in Section 4 of the document E&R Appendix B (revised), pages 246 to 255.⁶</p>
110622	<p>The submitter notes that the only oxamyl product registered in New Zealand is applied directly into furrows during planting of seedling carrot plants. The submitter considers that the non-contact period is not relevant for this method of application, and does not support non-contact periods for Vydate L in its current form.</p>	<p>The staff note the submitter's comments. The requirements of control E3, and any associated non-contact periods, only apply for plants that are likely to flower within the non-contact period and if the plant is likely to be visited by bees. Although the registered use patterns are not likely to fit into this timeframe, the HSNO approval for this substance does not restrict use to particular use patterns. As a safeguard against use of the substance for which the requirements of this control apply, the staff consider that this control and proposed non-contact periods apply. It may be beneficial for importers or manufacturers to provide explanations of use patterns that are not considered to be subject to non-contact periods on their product labels.</p>

Impact on staff proposals:

The staff consider that the issues raised by submitters in relation to the risk assessment and the data used do not necessitate any changes the initial staff proposals regarding the duration of the proposed non-contact periods.

2.4. Māori concerns

Submission number	Submitter comment	Staff response
110613	<p>The submitter indicates that non-contact periods will provide protection for bees resulting from ingestion or contact with residues of these substances. This is of benefit to Māori and Pākehā alike. The submitter questions whether the data used to derive the proposed non-contact</p>	<p>Honey bees are used as representative species but little is known about other bee species' sensitivity. The information used by the staff is considered to be the best available in relation to these substances. The staff note that the proposed controls do not distinguish between honey bees and native species, and are expected to offer</p>

⁶ <http://www.epa.govt.nz/search-databases/Pages/applications-details.aspx?applID=APP202142#>

Submission number	Submitter comment	Staff response
	periods to protect honey bees is relevant and will provide sufficient protection to native bee species or other pollinators.	protection for those species. Regarding other pollinators, which can be other kinds of insects or birds or bats or reptiles, this is outside of the scope of this modified re-assessment, which is specifically looking at non-contact periods for protection of bees.
110616	The submitter does not support use of these substances, citing the impact on the ability of Māori to fulfil their duty as Kaitiaki, as well as the human and environmental toxicity, as reasons for this position.	Opposition to continued use of these substances is noted. The staff would like to highlight that approval revocation is not within the scope of this application, as the modified reassessment pathway does not provide the HSNO decision makers with the power to do so.
110620	The submitter indicates that annual surveys on bee populations should form part of the controls to measure the effectiveness of the controls in place.	The staff consider that bee population monitoring falls outside the scope of any of the individual approvals, and is not intended to manage a specific risk associated with use of a substance. Such work could be undertaken and be used as the basis for a further application to establish grounds for reassessment if the results identified specific substances as the cause of an observed adverse effect.

Impact on staff proposals:

The staff consider that the issues raised in the submissions do not necessitate any changes to the staffs initial proposals regarding the implementation of the proposed non-contact periods.

3. EPA staff's updated recommendations

Upon consideration of the information received through submissions, the staff consider that the preliminary recommendations for the substances covered by this application should be modified to include a requirement to detail relevant non-contact periods on the product labels of the affected substances.

Accordingly, the staff propose the following modification to the control titled Control/Label Statement R-9: Label warning of effects on bees:

For acephate, dimethoate, methomyl or oxamyl containing substances

CONTROL/LABEL STATEMENT R-9: Label warning of effects on bees

- (1) A person must not supply a hazardous substance to any other person unless the substance label shows the following statement (or equivalent):

This product is toxic to bees. Do not apply this product to any plant or tree likely to be visited by bees—

- (a) at the time of application; or*
- (b) immediately after application until spray has dried; or*
- (c) in areas where bees are foraging; or*
- (d) if the plant or tree is likely to flower after application of the substance within [X]⁷ days.*

- (2) A person who is in charge of a hazardous substance must ensure that the substance label shows the information required by (1).

For methamidophos containing substances

CONTROL/LABEL STATEMENT R-9: Label warning of effects on bees

- (1) A person must not supply a hazardous substance to any other person unless the substance label shows the following statement (or equivalent):

This product is toxic to bees. Do not apply this product to any plant or tree likely to be visited by bees on the day of application, unless bees have left the area and have finished foraging for the day (i.e. after dusk).

- (2) A person who is in charge of a hazardous substance must ensure that the substance label shows the information required by (1).

The staff's proposed non-contact periods remain unchanged from the timeframes specified in the application form, and are reproduced in Table 4.

Table 4: Proposed non-contact periods and the affected approvals.

Substance	Proposed non-contact period	Approvals to which the non-contact period applied
Acephate	7	HSR000154
		HSR000155
		HSR000156
		HSR000157
		HSR000158
Dimethoate	7	HSR000188
		HSR000191
		HSR000193
		HSR000965
		HSR100129
Methamidophos	None.	HSR000203

⁷ where [X] is the appropriate non-contact period as detailed in Table 4.

Substance	Proposed non-contact period	Approvals to which the non-contact period applied
	<i>NB: application is restricted to after bees have left application area for the day.</i>	HSR000226
Methomyl	8	HSR000584 HSR007761
Oxamyl	10	HSR000791

3.1. Revised controls

The revised controls proposed for the substances covered by this application are detailed in the document titled E&R Appendix A: Controls (revised).⁸

⁸ <http://www.epa.govt.nz/search-databases/Pages/applications-details.aspx?applID=APP202142#>