



APPLICATION FORM

MODIFIED REASSESSMENT

Application for a Modified Reassessment

under section 63A of the Hazardous Substances and New Organisms Act 1996

Send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140
OR email to: HSApplications@epa.govt.nz

Name of substance(s):

Approvals for plant protection products containing acephate, dimethoate, methamidophos, methomyl or oxamyl

Applicant:

Rob Forlong, Chief Executive, Environmental Protection Authority

Date:

8 July 2014

APPLICANT CHECKLIST

- Mandatory sections filled out
- Appendices enclosed
- Fees enclosed
- Signed and dated

OFFICE USE ONLY

Application code

Date received

EPA contact

Initial fees paid \$

Application version no.

1. Applicant details

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2. Type of application

2.1. The approvals being reassessed

Substances containing acephate

HSR000154 – Soluble concentrate containing 195 g/litre acephate. Also contains ethylene glycol

HSR000155 - Water soluble powder containing 750 - 970 g/kg acephate

HSR000156 - Emulsifiable concentrate containing 45 g/litre acephate and 8.8 g/litre myclobutanil

HSR000157 - Emulsifiable concentrate containing 45 g/litre acephate and 39 g/litre triforine

HSR000158 - Emulsifiable concentrate containing 22.5 g/litre acephate and 19.5 g/litre triforine

Substances containing dimethoate

HSR000188 - Emulsifiable concentrate containing 400 g/litre dimethoate

HSR000191 - Emulsifiable concentrate containing 100 g/litre dimethoate

HSR000193 - Emulsifiable concentrate containing 500 g/litre dimethoate

HSR000965 - Perfekthion S-1

HSR100129 – Danadim

Substances containing methamidophos

HSR000203 - Soluble concentrate containing 600 g/litre methamidophos (Substance B)

HSR000226 - Soluble concentrate containing 600 g/litre methamidophos (Substance A)

Substances containing methomyl

HSR000584 - Soluble concentrate containing 200 g/litre methomyl

HSR007761 – Armourcrop Insecticide

Substances containing oxamyl

HSR000791 - Soluble concentrate containing 240 g/litre oxamyl

2.2. Specific aspect of the approval being reassessed

The intention of this application is to apply appropriate *non-contact periods* to the substances covered by the approvals listed in section 2.1. Non-contact periods refer to a period of time in advance of a plant or tree flowering during which no application of the substance may occur (refer to section 6.1). Non-contact periods may be

established under control E3 (Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001, regulation 49(1)(b)(ii) and (2) in order to further protect against post-application exposure of bees to harmful pesticides.

2.3. Grounds for the reassessment

The Decision Making Committee for application APP202033 (“the Committee”) determined that grounds for the reassessment of approvals for plant protection substances containing acephate, dimethoate, methamidophos, methomyl or oxamyl exist.

In reaching its decision¹ the Committee decided the legislative basis to undertake a reassessment is that significant new information relating to the effects of the substances exists. This information was considered new as it had not been presented to the decision-making committee for the EPA’s reassessment of Organophosphate and Carbamate plant protection substances (APP201045),² during which the non-contact periods that previously applied to these substances were removed.

Additionally, the Committee considered that reviewing the setting of non-contact periods is appropriate in the context of the overall purpose and spirit of the HSNO Act.

The Committee noted that because the proposed changes related to only one aspect of the approvals (i.e. the setting of non-contact periods), that any resulting application would be a Modified Reassessment under s63A of the Act.

2.4. Consultation

No specific consultation has been undertaken prior to compiling this application.

The applicant notes that information has already been provided by [Māori as part of the OPC reassessment \(APP201045\)](#). The applicant does not consider that the proposals detailed in this application will present any significant adverse effects on outcomes of interest to Māori. Additionally, the proposals are expected to be beneficial to Māori interests, particularly in the agricultural, honey and bee industries. Furthermore, the proposals would implement measures to protect bees, and should assist Māori in their role as kaitiaki.

The applicant notes that there was significant engagement with users and interested parties during the recent reassessment application, APP201045. The information provided during the processing of APP201045, through

¹ APP202033 Decision report: http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP202033_APP202033_Decision.pdf

² APP201045 Decision report: http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP201045_APP201045_Decision_FINAL.pdf

targeted engagement, submissions and at the hearings, was considered to be sufficient to inform the compilation of this application. Additionally, stakeholders were informed at the time of lodgement of the application to establish grounds for reassessment that, if grounds were established:

- a modified reassessment would be undertaken; and
- the modified reassessment application process would provide an opportunity to be involved in the decision-making process, through public submissions and hearings.

3. Information on the substances

3.1. The unequivocal identification of the substance

The substances affected by this application are those covered by approvals for plant protection products containing any of the following organophosphate or carbamate active ingredients: acephate, dimethoate, methamidophos, methomyl or oxamyl.

3.2. Information on the chemical, physical and hazardous properties of the substance

The scope of this application does not include review or amendment of the classifications of the affected substances.

The following table details the legal classifications for the substances covered by this application:

Substance identifier (as approved) and known Trade name	HSNO Approval number	HSNO hazard classification
Soluble concentrate containing 195 g/litre acephate. Also contains ethylene glycol Trade name: Orthene Liquid	HSR000154	6.1D (oral), 6.3A, 6.4A, 6.8A, 6.8C, 6.9A, 9.1D, 9.3C, 9.4B
Water soluble powder containing 750 - 970 g/kg acephate Trade names: Orthene WSG, Raider	HSR000155	6.1D (oral), 6.8A, 6.9A, 9.1D, 9.3B, 9.4A
Emulsifiable concentrate containing 45 g/litre acephate and 8.8 g/litre myclobutanil Trade name: Shield	HSR000156	6.8B, 6.9B, 9.1C, 9.3C, 9.4B
Emulsifiable concentrate containing 45 g/litre acephate	HSR000157	3.1D, 6.1E (oral), 8.2B, 8.3A, 6.8A, 6.8C, 6.9B, 9.1D, 9.3C,

Substance identifier (as approved) and known Trade name	HSNO Approval number	HSNO hazard classification
and 39 g/litre triforine Trade name: Saprene		9.4B
Emulsifiable concentrate containing 22.5 g/litre acephate and 19.5 g/litre triforine Trade name: McGregor's Rose and Shrub Spray	HSR000158	6.1E (oral), 6.3A, 8.3A, 6.8A, 6.8C, 6.9B, 9.3C, 9.4C
Emulsifiable concentrate containing 400 g/litre dimethoate Trade name: Dimezyl 40EC	HSR000188	3.1C, 6.1D (oral), 6.1E (aspiration), 6.4A, 6.8B, 6.9A, 9.1B, 9.2B, 9.3A, 9.4A
Emulsifiable concentrate containing 100 g/litre dimethoate Trade name: Garden King Rogor 100	HSR000191	3.1D, 6.1D (oral), 6.1E (aspiration), 6.3B, 6.4A, 6.8B, 6.9A, 9.1B, 9.2D, 9.3B, 9.4A
Emulsifiable concentrate containing 500 g/litre dimethoate Trade names: Perfekthion S, Perigen 500 Spray & Residual Insecticide	HSR000193	3.1C, 6.1D (oral), 6.1D (dermal), 6.3B, 6.4A, 6.8A, 6.9A, 9.1B, 9.2B, 9.3A, 9.4A
Perfekthion S-1 Trade names: DIME, PERFEKTHION S, Rogor E	HSR000965	3.1C, 6.1D (oral), 6.1D (dermal), 6.4A, 6.8B, 6.9A, 9.1B, 9.2B, 9.3A, 9.4A
Danadim Trade name: Danadim Progress	HSR100129	3.1C, 6.1C (oral), 6.5A, 6.5B, 6.8B, 6.9A, 9.1B, 9.2B, 9.3A, 9.4A
Soluble concentrate containing 600 g/litre methamidophos (Substance B) Trade name: Monitor	HSR000203	3.1D, 6.1B (oral), 6.1B (dermal), 6.1B (inhalation), 8.2C, 8.3A, 6.9A, 9.1A, 9.2B, 9.3A, 9.4A
Soluble concentrate containing 600 g/litre methamidophos (Substance A) Trade names: Metafort 60SL, Methafos 600, Tamaron	HSR000226	3.1D, 6.1B (oral), 6.1B (dermal), 6.1B (inhalation), 8.2C, 8.3A, 6.9A, 9.1A, 9.2B, 9.3A, 9.4A
Soluble concentrate containing 200 g/litre methomyl Trade names: ORION METHOMYL 200SL, DuPont	HSR000584	3.1B, 6.1C (oral), 6.1D (dermal), 6.1D (inhalation), 6.4A, 6.8B, 6.9A, 9.1A, 9.2D, 9.3B, 9.4A

Substance identifier (as approved) and known Trade name	HSNO Approval number	HSNO hazard classification
Lannate L insecticide		
Armourcrop Insecticide	HSR007761	6.1D (oral), 6.4A, 6.8B, 6.9B, 9.1A, 9.3C, 9.4B
Soluble concentrate containing 240 g/litre oxamyl Trade name: DuPont Vydate L oxamyl insecticide/nematicide	HSR000791	3.1C, 6.1B (oral), 6.1D (dermal), 6.1B (inhalation), 6.4A, 6.8B, 6.9A, 9.1B, 9.2D, 9.3A, 9.4A

3.3. Identification of the controls on the substances

The complete list of controls that apply to the approvals affected by this application are detailed in Appendix A.

This application focuses on the application of appropriate non-contact periods, specified as part of control E3 (regulation 49 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001. This control is applied to substances that are classified as ecotoxic to terrestrial invertebrates (HSNO class 9.4). The purpose of this control is to protect terrestrial invertebrates, in particular beneficial insects, such as bees and other pollinators, from the adverse effects that can arise from the use of certain ecotoxic substances. The control achieves this by prohibiting a substance from being applied in particular locations and in a manner that may result in those terrestrial invertebrates being exposed. Non-contact periods are set in 49(1)(b)(ii):

49 Use of substances ecotoxic to terrestrial invertebrates

- (1) *A person must not apply a class 9.4 substance in an application area—*
- (a) *if bees are foraging in the area and the substance is in a form in which bees are likely to be exposed to it; or*
 - (b) *to any plant or tree that is likely to be visited by bees if—*
 - (i) *the plant or tree is in open flower or part bloom; or*
 - (ii) *the plant or tree is likely to flower after application of the substance within a period specified by the Authority.*
- (2) *The period specified by the Authority must not be longer than 10 days.*

Control E3 for each substance in Appendix A includes the relevant non-contact period, as proposed in this application.

3.4. The proposal to modify the approval of the substances

This application seeks to assess the post-application risks to bees posed by substances that contain any of the identified active ingredients, and proposes to apply appropriate non-contact periods where the EPA staff (“the staff”) risk assessment indicates that additional risk mitigation is required. The staff undertook a review of the available data regarding the persistence of ecotoxic effects of acephate, dimethoate, methamidophos, methomyl and oxamyl on bees in order to determine if a **non-contact period** should be defined. Further details of the assessment undertaken can be found in Appendix B.

On the basis of this data review the staff consider that the following non-contact periods should be specified for substances containing the following active ingredients:

Substance	Previous non-contact period ³	Proposed non-contact period	Approvals to which the non-contact period applied
	Days		
Acephate	7	7	HSR000154
			HSR000155
			HSR000156
			HSR000157
			HSR000158
Dimethoate	7	7	HSR000188
			HSR000191
			HSR000193
			HSR000965
			HSR100129
Methamidophos	7	None	HSR000203
			HSR000226
Methomyl	10	8	HSR000584
			HSR007761

³ Non-contact periods that were in place prior to the decision on APP201045 (June 2013).

Substance	Previous non-contact period ³	Proposed non-contact period	Approvals to which the non-contact period applied
	Days		
Oxamyl	10	10	HSR000791

Although non-contact periods are not proposed for methamidophos, the applicant proposes that application of methamidophos substances should be permitted in the evening only once bees have stopped visiting the application area and returned to their apiaries or hives for the night. Accordingly, it is proposed that, for approvals HSR000203 and HSR000226, clauses (1) and (2) of regulation 49 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001 (control E3) are replaced by the following:

49 Use of substances ecotoxic to terrestrial invertebrates

A person must not apply this substance in an application area—

- (a) *if bees are foraging in the area and the substance is in a form in which bees are likely to be exposed to it; or*
- (b) *to any plant or tree that is likely to be visited by bees if the plant or tree is in open flower or part bloom, until such time as bees have left the area and have finished foraging for the day.*

3.5. Commercial sensitivity

The applicant does not consider that there are any significant issues regarding commercial sensitivity associated with the proposed modifications because the proposals relate to these substances by virtue of the fact that they contain particular active ingredients. This information, along with any relevant use pattern information, is already in the public domain.

The applicant notes that, in undertaking this review, study reports have been used that were provided to the EPA in confidence as part of the data package for a different application. Identification of these studies is considered to be commercially sensitive and has not been included in the non-confidential section of this application. A non-confidential summary of the report is included (Appendix B).

4. Risks, costs and benefits

4.1. Identification of all the effects associated with the reassessment proposal (section 63A(6)(a))

Prior to the decision made on the reassessment application APP201045, all of the affected approvals were subject to the non-contact periods specified in section 3.4. Accordingly, the adverse effects associated with implementation

of the proposals detailed in this application are not considered to be of major significance because these restrictions have been in place since the HSNO approval for the substances were originally granted.

These non-contact periods were removed as a result of the reassessment where the risks to bees were considered to arise from direct exposure to pesticide spray. However, grounds to reassess this specific aspect of the approvals have been established on the basis that significant information was not presented to, or did not form part of the material considered by the decision makers. This information highlighted a risk to bees from exposure to pesticide residues post-application. The purpose of this application is to review the necessity for establishing and setting non-contact periods for these substances, in order to ensure that bees are not exposed to levels of residual pesticides that may have a toxic or fatal effect.

Protection of bees from post-application exposure

Currently, the approvals to be reassessed do not have any non-contact periods set. Compliance with control E3 will ensure that bees are not exposed to levels of pesticides that may give rise to adverse health effects during spraying. However, there are no control measures to protect bees from the post-application exposure to these substances. The toxicities of the residues of the substances identified in this application are considered to persist for significant periods of time after application. Exposure to residues dried on the surfaces of plant foliage, or within the pollen/nectar/guttation fluid of a plant that a bee is likely to visit, could give rise to adverse effects for an extended period of time, such as toxicity or reduced flight intensity. The measures proposed (i.e. use of non-contact periods) are intended to mitigate the risks arising from the extended residual toxicities of these substances so that bees and other pollinators are not adversely affected.

Timing of pesticide applications

If non-contact periods were implemented, applicators will need to take these restrictions into account when working out the timing of pesticide applications to ensure that flowering is not likely to occur before the non-contact period has elapsed. This will restrict and potentially prevent the use of certain pesticides at certain times of crop growth. This control is of particular importance for use of pesticides on crops that flower continuously. In such situations, the staff consider that no safe application period can be specified and alternative insecticide control options would be required. The staff note that this is no different to the restrictions that have been in place on these substances since the approvals were originally granted. An exception to this situation is that, based on the proposals in section 3.4, use of methamidophos substances would be permitted to be used once bees have finished foraging and left the application area.

Submitters argued during the processing of APP201045 that imposing non-contact periods is impractical and unnecessary. If non-contact periods are re-implemented, a potential consequence is that application of the substances may take place at non-optimum times (e.g. in terms of effectiveness, growth stage, operational considerations), or result in non-compliance with the restrictions imposed in order to apply the substances at a time that the user considers to be more beneficial.

Potential impacts on sales or use of the substances

Imposing restrictions on when these products may be applied may result in applicators using less of the substance, or moving to alternative substances that are not subject to non-contact periods. This could potentially have a detrimental impact on sales, in comparison to the levels of sales when no such restrictions were in place. However, given that these restrictions have been in place since the HSNO approval for the substances were originally granted, this is not considered to be a significant concern.

4.2. Assessment of the risks associated with the reassessment proposal

While the restrictions may make the substances more difficult or less convenient to use for applicators in contrast to alternatives with no non-contact periods specified, the change in use associated with this proposal should be no more of an imposition than the restrictions that have been in place for many years for these substances.

The proposals have taken into account available current data and literature, and, as a result, the restrictions proposed are now less stringent than the original HSNO approvals, with no non-contact periods proposed for methamidophos products, and reduced non-contact periods proposed for methomyl.

On the basis of the staff evaluations for each substance in this approval, which are summarised below and detailed in Appendix B, the applicant considers that there are significant risks associated with maintaining the approvals with no non-contact periods set. Without the proposed restrictions, there are no control measures in place that will protect bees from being exposed to residues of the pesticides applied. Given that these pesticides remain toxic to bees for an extended period after application, the risks to bees from post-application exposure are not being adequately managed if application is undertaken too close to the time at which plants flower and become attractive to bees.

The applicant considers that, in most instances, there are other approved insecticides that could be used as alternatives to the substances covered by this application. However, information provided during the processing of APP201045,⁴ indicated that certain substances covered by this application were considered to be critical for certain sectors (e.g. acephate use for citrus production), so moving to alternative insecticides may not be feasible or practical. Additionally, reliance on other chemical classes of insecticide has implications on resistance management programmes. The applicant acknowledges that the proposed non-contact periods will make it more restrictive to use these substances but considers that these restrictions can be justified in order to afford bees protection against extended residual toxicity of these insecticides. Furthermore, such restrictions have been in place since the HSNO approval for the substances were originally granted, and the proposed restrictions are, at most, as restrictive as previously imposed, and less restrictive in some instances.

⁴ APP201045 Consultation report:
http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP201045_Consultation%20Report.pdf

Post-application effects of acephate

Significant new information from the US EPA⁵ regarding the post application effects of acephate has been reviewed, which consisted of aged residue studies and foliar residue degradation studies.

The aged residue studies were carried out at lower rates than the maximum permitted application rates in New Zealand. Even at these lower rates, significant mortality of bees was observed four days after application.

The degradation rate (DT50) of dislodgeable foliar residues responsible for the residual contact toxicity, observed in different crops and for different use patterns, varies between 3.08 and 5.92 days for combined acephate and methamidophos.

The staff conclude that no information is available to demonstrate that, under New Zealand use conditions, the residual ecotoxicity of acephate does not present a risk to bees post-application. Accordingly, it is proposed that the use of acephate should be controlled to minimise these post-application exposure risks. It is proposed to reinstate a non-contact period of 7 days for substances containing acephate.

Post-application effects of methamidophos

Significant new information from the European Commission Health & Consumer Protection Directorate-General⁶ has been reviewed, which consisted of a cage and field study.

This study demonstrates that, whilst methamidaphos is ecotoxic to bees immediately after application, the toxicity of methamidaphos rapidly decreases post application. Mortality associated with methamidaphos is limited to the first day after application.

Accordingly, it is proposed that a non-contact period is not required to protect bees from post-application exposure to methamidaphos. It is proposed that the methamidophos substances should only be applied in the evening, to provide sufficient time for the residues to reduce sufficiently to ensure that post-application risks to bees are acceptable.

Avoidance of spraying at times when bees are likely to be foraging will still be required, as the risks associated with direct contact with the pesticide spray remain.

Post-application effects of dimethoate

Significant new information has been reviewed by the EPA, sourced from overseas regulatory reviews, from studies provided to the EPA as part of the application dossier, processed after completion of APP201045, for approval of a new hazardous substance, and from the literature. Dimethoate is commonly used as a toxic reference

⁵ Re-registration documents for acephate, with particular reference to the ecotoxicology appendices
<http://www.epa.gov/espp/litstatus/effects/redleg-frog/acephate/appendicies.pdf>

⁶ European Commission Health & Consumer Protection Directorate-General. Review report for the active substance methamidophos. SANCO/4341/2000 - rev. 5 (14 December 2006)
http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance_detail

in standard GLP⁷ compliant studies performed to evaluate the effects of other substances. The information reviewed consisted of data on the following:

- Extended laboratory residue studies
- Semi-field (tunnel) test
- Field testing
- Dislodgeable foliar residues of dimethoate from different crops.

The staff consider that the data available for dimethoate is of a high quality, with information on application rates that relate to New Zealand use patterns. These data demonstrate that dimethoate exhibits residual toxicity that increases bee mortality up to 7 days after application.

Based on this information, post-application exposure risks to bees need to be managed, and a non-contact period of 7 days is proposed.

Post-application effects of methomyl

Significant new information has been reviewed by the EPA, sourced from the available literature and overseas regulatory reviews. This information consisted of field test study data, semi-field test review information and dislodgeable foliar residue data.

The field study undertaken in New Zealand, using application rates of 0.56 kg methomyl / ha,⁸ showed significant ecotoxic effects on bees for up to 8 days after application. Accordingly, a non-contact period of 8 days is proposed in order to manage this risk.

Post-application effects of oxamyl

Significant new information from the US EPA⁹ was reviewed. The US EPA noted that a foliage residue study indicates that oxamyl “may remain toxic to bees for as long as 6 days after treatment”. The staff note that this study was carried out using application rates significantly lower than those permitted in New Zealand.

Accordingly, the duration of adverse effect is expected to be longer in New Zealand than exhibited in the study, and that a non-contact period of 10 days is sought to apply to oxamyl insecticides.

Conclusion

If application of these substances is carried out at a time that does not protect against the post-application toxicity, the adverse effects are considered to be moderate, given that significant, local damage to colonies of bees could be expected to occur. The likelihood of such an adverse effect occurring is affected by many factors (such as attractiveness of target crop, synchronicity of flowering of the plants, attractiveness of competing food sources, water availability and chemical uptake into guttation fluid). However, an adverse effect is considered reasonably

⁷ Good Laboratory Practice

⁸ This rate is slightly higher than the maximum application rate of 0.48 kg methomyl / ha., imposed as a result of the OPC reassessment decision

⁹ Interim Reregistration Eligibility Decision (IRED) about Oxamyl (US EPA 738-R-00-015, October 2000)
<http://www.epa.gov/oppsrrd1/REDs/0253ired.pdf>

possible under normal operating conditions, which means that there are significant (i.e. non-negligible) risks to be addressed if bees are attracted to treated plants and come into contact with toxic pesticide residues.

It should be noted, however, that the corresponding risks associated with methamidaphos substances are considered to be sufficiently low that non-contact periods are not required to be specified, as the residual toxicity only presents a significant exposure risk to bees for a short time after application. However, the application of methamidaphos substances should be restricted to the evening, after bees have finished foraging. This will provide sufficient time for the toxicity of the residues to reduce sufficiently overnight to not pose a danger to bees when they subsequently recommence foraging on the treated flowering plants.

4.3. Assessment of the costs associated with the reassessment proposal

The staff note comments regarding non-contact periods have been received from an industry group representing a number of horticultural sector growers, both during and after the reassessment application was completed. These comments focused on the practicality of implementing non-contact periods and the impact that such a control has on use of the substances in question, particularly for crops which are continually flowering such as citrus trees. Growers have indicated that they consider the risks to bees are adequately managed by undertaking applications at times when bees are not active, such as early morning or in the evening.

Although costs have not been expressly determined, the effects of these proposals may introduce costs in terms of use of the substances in question (e.g. when the substances may be used, reduced effectiveness of substances due to use permitted only at non-optimum times). However, the EPA notes that these proposals simply reinstate non-contact periods, which had been requirements of the affected approvals up until the decision on application APP201045 in June 2013. Indeed, the proposals in the current application, as a whole, are less restrictive than previously prescribed. Accordingly, the EPA considers the change to the costs associated with the proposed non-contact periods that were imposed on these substances for the majority of their approval lifetimes to be negligible, given that the overall level of restriction is proposed to be reduced.

4.4. Assessment of the benefits associated with the reassessment proposal

The staff consider the principal benefit of the proposal is associated with the protection of bees through the reinstatement of appropriate non-contact periods. These risk mitigation measures will help to prevent environmental exposure to non-target insects, in particular beneficial insects. The flow-on effects of protection of beneficial pollinators is to ensure that pollination processes, which are vital for crop production, are not impacted by inappropriate insecticide application.

In a recent report by the Ministry for Primary Industries on apiculture¹⁰ in 2013 honey exports were over 8000 tonnes, valued at \$145 million, with 4279 registered beekeepers in New Zealand. The Federated Farmers of New Zealand state that “pollination provided by the bee industry contributes at least \$4.5 billion annually to New Zealand's economy and underpins a further \$12.5 billion of export revenue from the horticultural, arable, pastoral and beekeeping sectors”.¹¹ Many horticultural sectors are reliant on commercial pollination as part of their production operations, such as kiwifruit and fruit orchards. Pollinators are a vital component of the food chain, and protection of pollinators is critical to the New Zealand economy. Mitigation of exposure to agricultural pesticides is vital to assist in safeguarding the contribution of bees.

4.5. Assessment of any particular risks, costs and benefits which arise from the relationship of Māori and their culture and traditions with their taonga, or which are, for other reasons, of particular relevance to Māori

The intention of this application to apply appropriate non-contact periods. The expected benefits of bee protection should aid Māori in their role as kaitiaki and protecting the 28 native bee species as well as the introduced species.

Given bees are effective pollinators, non-contact periods will help to protect bees, and should support the agricultural and honey sectors, of which Māori are large contributors.

The Crown's duty of active protection is the obligation to take positive steps to ensure Māori interests are protected. In light of the points mentioned above, the applicant considers that these proposals should help to actively protect the interests of Māori.

Accordingly, the applicant considers that there are not likely to be any risks to the interests of Māori as a result of this application, and that the likely effects to arise from these proposals will be beneficial to supporting those interests.

5. International considerations

5.1. The best international practices and standards for the safe management of the substance (section 63A(6)(b))

Information that was used in the EPA assessment was largely based on overseas regulatory activity and documents. Non-contact periods are not widely used by regulatory authorities as a protection measure to manage the risks associated with exposure to toxic residues, but extended residual toxicity is acknowledged to present a

¹⁰ Apiculture: Ministry for Primary Industries 2013 apiculture monitoring programme, 16 December 2013, <http://www.mpi.govt.nz/news-resources/publications.aspx?title=Apiculture>

¹¹ <http://www.fedfarm.org.nz/advocacy/National-Policy/Bees-Issues.asp>, (Accessed 26/06/14)

real threat to pollinators. Some overseas product labels specifically include statements specifying non-contact periods for dimethoate. It is unclear why this is the case. Non-contact periods are included in guidance material produced in the United States of America to assist applicators to avoid causing adverse effects to pollinators.¹² Additionally, regulatory advice for applicators commonly includes statements such as “Choose pesticides with the lowest hazard rating for bees, particularly the lowest residual toxic effect”.¹³ Managing risks to bees is a global concern, including those that arise through long-lasting residual toxicity, and is in line with global regulatory action. Implementing appropriate non-contact periods is the most effective method to achieve this. Implementing measures to best protect bees from the adverse effects of pesticides, such as protecting against the adverse effects that could arise as a consequence of the extended residual toxicity of these insecticides, will align with international best practice.

5.2. International obligations and treaties

The staff do not consider that any international obligations or treaties will be affected by the proposals in this application.

6. Hazardous substance knowledge

6.1. A glossary of scientific and technical terms used in the application

Non-contact period means the period of time that must elapse between application of a substance onto a plant or tree, and when that plant or tree begins to flower. A non-contact period is the period of time referred to in regulation 49(1)(b)(ii) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001.

This time period is intended to provide protection to bees, and other insect pollinators, by ensuring that sufficient time has passed to ensure that the residual pesticide levels are sufficiently low when the plants or trees that have been treated begin to flower and are attractive to bees.

¹² E.g. How to reduce bee poisoning from pesticides, Oregon State University, 2013
<http://www.ipm.ucdavis.edu/PDF/PMG/pnw591.pdf>

¹³ E.g. Reducing harm to honey bees from pesticides, Government of South Australia,
http://www.pir.sa.gov.au/_data/assets/pdf_file/0006/126294/FSReducingharmtoHoneyBeesfromPesticides1313.pdf

6.2. Other information considered relevant to this application not already included

For some pesticide chemicals prevention of spraying during flowering is insufficient to manage the exposure risks to beneficial insects. This is particularly the case when the effects of exposure to a pesticide chemical may last a number of days post-application, meaning that adverse effects may occur for a significant time after application, even if the target plant or tree was not in flower at the time of application. However, the control allows the Authority to specify a period of time in advance of a plant or tree flowering during which no application may occur (a “non-contact time”), in order to further protect against post-application exposure of bees.

During the process of transferring the affected substances into the HSNO Act, and subsequent approvals under Part 5 of the Act, the non-contact times specified by the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the Ministry for Primary Industries (MPI) were adopted as the time periods permitted to be specified under (1)(b)(ii) of regulation 49. The following variation was applied to control E3 for the original HSNO approvals covered by this application:

Restriction on application of certain ecotoxic substances

- (1) *This substance contains one or more component listed in the table below. For the purposes of regulation 49(1)(b)(ii) of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001, the Authority specifies the period opposite.*
- (2) *The periods specified below are the number of days before flowering during which the substance must not contact plants if the plants are likely to be visited by bees.*

Component	Days
Acephate	7
Dimethoate	7
Methamidophos	7
Methomyl	10
Oxamyl	10

In the EPA’s reassessment of organophosphate and carbamate plant protection products (application APP201045), the staff considered that the risks to bees arose as a consequence of direct exposure to the spray solution. Accordingly, the staff’s proposals, which were subsequently adopted by the decision making Committee for APP201045, did not include non-contact periods for the substance approvals being specified under regulation 49(1)(b)(ii). The applicant considers that information reviewed since the time this decision was made, which was not considered before this time, indicates that these application of these substances present significant post-application exposure risks to bees.

7. Summary of public information

7.1. Name of the substance for the public register

Plant protection products containing acephate, dimethoate, methamidophos, methomyl or oxamyl

7.2. Purpose of the application for the public register

To review and implement appropriate non-contact periods for certain organophosphate or carbamate plant protection substances, in order to protect bees, and other insect pollinators, against adverse effects arising from post-application exposure to the substances.

7.3. Executive summary

The applicant proposes that the following non-contact periods should be applied to plant protection products containing acephate, dimethoate, methamidophos, methomyl and oxamyl:

Active ingredient component	Non-contact period (Days)
Acephate	7
Dimethoate	7
Methamidophos	None
Methomyl	8
Oxamyl	10

In its recent reassessment of organophosphate and carbamate plant protection substances (APP201045), the EPA considered that the risks to bees from the use of these products arose principally from direct contact during spraying. Accordingly, the existing non-contact periods were removed for the specified active ingredients. However, grounds to reassess this specific aspect of the approvals have been established noting that significant information was available regarding the persistent, post-application ecotoxic effects on beneficial insects of a number of the active ingredients and their formulations. Upon review of this new information, the EPA propose to reinstate non-contact periods in order to manage the post-application risks to bees.

The applicant considers that there are significant risks for some substances associated with maintaining these approvals without non-contact periods set, as the risks to bees from post-application exposure are not being adequately managed. Use of methamidophos should be restricted to the evening when bees have returned to apiaries or hives, which will provide sufficient time for the toxicity to reduce before bees return to the area the following day.

The benefits associated with the proposals relate to the protection of bees, and ensuring that beneficial pollinator insects, and the subsequent pollination of crops, are not adversely affected by use of these substances. It is considered that the proposed use of non-contact periods will provide for the active protection of Māori interests, such as assisting in the kaitiaki role of Māori and supporting the agricultural and honey sectors, to which Māori are large contributors, through the protection of insect pollinators.

The applicant notes that non-contact periods may impact on users by prohibiting application of substances at the most optimum time in terms of practicality or effectiveness. However, the applicant notes that non-contact periods were in place for these approvals from the time of their initial approval until the recent OPC reassessment decision, and that compliant use of these substances would have required adherence to these non-contact periods. The applicant notes that the proposed non-contact periods are no more restrictive than those previously imposed on these approvals.

8. Applicant's signature

R. Forlong

08/07/14

Signed

Date