Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

7 August 2015

Overview

Substance	OPC substances reassessment
Application code	APP202142
Application type	To modify an existing approval for a hazardous substance under Section 63A of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Application sub-type	Notified – Chief Executive initiated Modified Reassessment
Applicant	Environmental Protection Authority (EPA)
Purpose of the application	To apply appropriate non-contact periods to certain organophosphate or carbamate plant protection substances, in order to further protect against post-application exposure of bees to harmful pesticides.
Date application received	8 July 2014
Submission period	22 July 2014 to 16 September 2014
Submissions received	17 submissions were received
Hearing Date	17 February 2015
Consideration period	16 March 2015 to 7 August 2015
Considered by	A decision-making Committee of the Environmental Protection Authority ("the Committee"): Ms Helen Atkins (Chair) Dr John Taylor Dr Louise Malone
Decision	Approved with Controls

1. Executive summary

1.1. The Chief Executive of the EPA applied for a modified reassessment of 15 approvals for plant protection products containing acephate, dimethoate, methamidophos, methomyl and oxamyl. The purpose of the application was to review the need to set non-contact periods under Regulation 49 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations and apply corresponding labelling controls.

1.2. A non-contact period is the time that must elapse between when the pesticide is last applied and when the plants are expected to flower. Non-contact periods are set to prevent bees from being exposed to pesticide residues that may remain at toxic levels for several days after they are applied.

1.3. Non-contact periods were applied to the substances covered by this reassessment until June 2013 when they were removed during the full reassessment of 28 organophosphate and carbamate (OPCs) plant protection products (APP201045); this application seeks to re-instate them.

1.4. Seventeen submissions were received from individuals, community and iwi groups, beekeepers, manufacturers and horticultural industry groups. The submissions presented a range of perspectives on the application from the perceived inability of the proposed controls to protect bees to the potential economic impact that not being able to use the substances during the non-contact periods would have on various horticultural industries. The submitters also raised questions about which bee species would be covered by the control, the application of the precautionary principle, and whether the grounds for reassessment were sufficient. These matters are addressed in detail in this decision.

1.5. The EPA staff prepared an Evaluation and Review (E&R) report which summarised the submissions and the scientific studies used to determine the proposed non-contact periods, and the staff's assessment of the available information. On the basis of the risk assessment the staff recommended applying a non-contact period for each active and corresponding labelling controls to inform users of the requirements.

1.6. After carefully considering all relevant information, the Committee decided that it had sufficient information to make a decision on this application.

1.7. The Committee considered that it was important to balance the environmental risks of not having non-contact periods with the economic risks to growers not being able to use particular pest control tools at key times. As a result the Committee has accepted the non-contact periods proposed by the staff but has applied specific crop-based exemptions to some active ingredients to manage the economic risks. The Committee have also decided to phase in the new requirements to accommodate the necessary changes to product labels.

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2. Background and historical context of the application

2.1. The EPA completed a reassessment of organophosphate and carbamate plant protection products (APP201045) in 2013. This was a full reassessment of 88 approvals.

2.2. During this reassessment the requirement for non-contact periods (i.e. a period of time in advance of a plant or tree flowering during which no application of the substance may occur) was removed from several substances because information provided to the Decision-Making Committee suggested that the risks to bees were posed only by direct exposure to the pesticide and not exposure to dried chemical residue on sprayed plants. This change to the controls is due to come into effect in July 2015.

2.3. Prior to the reassessment, the controls on the affected approvals had non-contact periods of up to 10 days, depending on the substance. Those controls dated back to previous legislative regimes and continued under the Hazardous Substances and New Organisms Act 1996 ("the Act") by virtue of the transfer period from the old regimes to the HSNO regime.

2.4. Shortly after the decision on APP201045 was publicly notified the National Beekeepers Association (NBA) raised concerns about the risks that dimethoate-containing substances could pose to bees after the substances were applied to plants.

2.5. The NBA's key concern was that pesticide residues could remain on the plants at levels that are toxic to bees for several days after the spray is applied, and bees could subsequently be affected by the pesticide even if the spray was applied in accordance with the current controls (i.e. no non-contact periods).

2.6. Subsequent investigation by the EPA staff ("the staff") showed that substances containing acephate, methamidophos, methomyl and oxamyl posed similar risks and that a modified reassessment should be completed to consider whether to re-instate non-contact periods for these substances.

3. Application process

3.1. The application was lodged pursuant to Section 63A of the Act.

3.2. At the time this application was formally received, there were 15 approvals for substances containing either: acephate, dimethoate, methamidophos, methomyl or oxamyl. Several commercial products can be covered by a single approval and it is often the case that some approvals are not actively used.

3.3. The application was publicly notified in accordance with Sections 63A and 53A of the Act.

3.4. The submission period was from 22 July 2014 to 16 September 2014. Seventeen submissions were received, including a group submission by Market Access Solutionz on behalf of several horticultural industry producer groups. Nine submitters requested to be heard at the hearing.

3.5. The Ministry for the Environment, WorkSafe New Zealand, the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the Ministry for Primary Industries (MPI), the Ministry of Health and the Department of Conservation (DOC) were advised of the application. No comments or submissions were received.

3.6. The submission received from Market Access Solutionz indicated that Arystra Life Sciences was undertaking further studies on acephate to support the submission. The report from this study was formally requested from Arysta Life Sciences in accordance with section 58 of the Act. Consequently the timeframe for commencement of a hearing was waived under section 59 of the Act, to allow time for this information to be received.

3.7. On 17 February 2015, a hearing was held at The Bay Plaza Hotel, Wellington. The staff presented the application and the EPA staff Evaluation and Review report (E&R). Nikki Johnson (Market Access Solutionz and Vegetables NZ), Rick Curtis (NZ Citrus Growers), Geoff Langford and Peter McIntyre (Strawberry Growers NZ), Ben Smith (Tomatoes NZ), Oliver Sutherland (Te Rūnanga o Ngāi Tahu), Malibu Hamilton (Clean Earth), Vera and Nora Van der Voorden, Paul and Joan Havemann, and Don MacLeod (NBA) spoke to their submissions.

3.8. The following information was considered by the Committee:

- the application
- the submissions
- the evaluation and review (E&R) report
- information presented at the hearing by the EPA staff (as the applicant), the submitters, and Ngā Kaihautū
- information and responses provided by the submitters at the Committee's request, which included:
    - an opinion from the EPA legal team on the definition of bees and the status of the grounds for reassessment
    - additional written comments from the NBA on the Market Access Solutionz submission
    - additional written comments from Arystra Life Sciences about the EPA staff's review of their study report.
    - A memo from the staff project team regarding legal advice on setting crop-specific controls, which had been provided to the Decision-Making Committee in relation to the original reassessment application in 2013 (APP201045).

3.9. The Committee considered that it had received sufficient information to proceed with its consideration of the application. Further comments on different aspects of this information can be found in the sections following.

4. Establishment of grounds for a reassessment

4.1. The reassessment (full or modified) of a substance is a two-stage process. The first stage is an application to establish grounds for reassessment under section 62 of the Act and the second stage is the application to reassess the substance under sections 63 or 63A of the Act.

4.2. An application for grounds for a modified reassessment is decided by a Decision-Making Committee of the EPA which for the avoidance of doubt in this case was not this Committee.

4.3. On 17 March 2014 the Chief Executive of the EPA applied to the EPA (Application APP202033) to determine whether grounds existed to undertake a modified reassessment to determine appropriate non-contact periods for plant protection products containing acephate, dimethoate, methamidophos, methomyl and oxamyl.

4.4. The application for grounds showed that there was relevant information on the persistence of these substances and their toxicity to bees which was not taken into account by the staff when they were developing the staff proposals for APP201045, nor was it put before the decision makers for consideration of that application. The Committee considering the grounds application therefore considered this significant new information and grounds for a modified reassessment were established.

4.5. The decision that grounds were established was made on 11 April 2014.

4.6. In their written and oral submissions on this application, Market Access Solutionz questioned the fairness of reassessing these controls within 18 months of the last reassessment, and challenged whether the information used to obtain grounds was indeed ‘new’.

4.7. The Committee sought legal advice as to whether or not it was at liberty to revisit the grounds decision.

4.8. The legal advice was that a reassessment comprises two separate and distinct steps, the grounds and the application for reassessment. Further, it was not within the scope of the delegation for this Decision-Making Committee to revisit the grounds decision which had been determined by a different Decision-Making Committee.

4.9. On the basis of this advice the Committee proceeded to assess this application in accordance with section 63A.

5. Purpose of the application

5.1. An application was made by the Chief Executive of the EPA, to determine the post-application risks to bees posed by plant protection products containing acephate, dimethoate, methamidophos, methomyl or oxamyl (specified in Table 1), and to apply appropriate non-contact periods where the risk assessment indicates that additional risk mitigation is required.

5.2. The current controls on these substances already prohibit substances containing these active ingredients being applied when bees are foraging. The control states that *"A person must not apply a class 9.4 substance in an application area if bees are foraging in the area and the substance is in a form in which bees are likely to be exposed to it" (s.49(1)(a)) or "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" (s.49(1)(b)(i)).* There is no proposal to change this aspect of the control.

6. Scope of the reassessment

6.1. Under section 63A(2) of the Act, the Committee may decide to vary the controls of any of the substances covered by a modified reassessment application but it cannot revoke an approval. As such, the Committee can only make decisions on matters that are within the scope of the application and which apply to the substance covered by the application. The Committee can make recommendations about additional matters such as EPA process or future reassessment work.

6.2. The Committee notes that some actions or changes requested by submitters are beyond the scope of this application, namely, requests to ban pesticides containing these active ingredients and issues relating to neonicotinoid pesticides.

6.3. Subject to the scope of the application, the Committee can vary the controls or proposed controls under section 63A(2)(a) of the Act to manage the risks identified during the reassessment process and it is not bound to simply granting or refusing the application made.

Controls to be reassessed

6.4. This application for a modified reassessment seeks to vary the control set by regulation 49 of the Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations (2001) by adding non-contact periods under regulation 49(1)(b)(ii) of that regulation. The associated label statement controls will need to be varied to reflect the changes to the control made under this modified reassessment. Regulation 49 of the Hazardous Substance (Classes 6,8 and 9) Regulations 2001

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.

6.5. The variation proposed by the applicant is that for substances containing acephate, dimethoate, methomyl and/or oxamyl, subclause (1)(b)(ii) and clause (2) of regulation 49 are replaced by the following subclause:

(ii) the plant or tree is likely to flower after application of the substance within X days

where X represents the proposed non-contact period, which is different for each active ingredient.

Table 1 proposed non-contact periods

Active ingredient	Proposed non-contact period (X) days
Acephate	7
Dimethoate	7
Methamidophos	0 (see 6.8 below)
Methomyl	8
Oxamyl	10

6.6. Therefore the proposal is that the final control will read:

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 [X] days

6.7. For substances containing methamidophos, the applicant proposes deleting subclauses (1) and (2) of regulation 49 and replacing them with the following wording:

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.

Definition of a non-contact period

6.8. Non-contact period means the period of time that must elapse between application of a substance to a plant (or tree), and when that plant is likely to begin to flower.

6.9. A non-contact period is intended to protect bees by limiting their exposure to pesticide residues on plants. The non-contact period is set to ensure that the concentration of the active ingredient of the pesticide on the plants is likely to be low enough to avoid harm to bees when the plant flowers and becomes attractive to these insects.

6.10. The term plants (or trees) in the control includes weeds and grass or other non-target plants, shelter belt trees and hedges, as well as commercially grown species.

Definition of a bee

6.11. The control in question specifically relates to bees rather than all insect pollinators. Several submitters questioned whether this control related specifically to honey bees (*Apis* species) or to all bees (taxonomic family Apidae) including bumble bees (*Bombus* species), other introduced bee species (approx. 13 species) and native bee species (approx. 28 species).

6.12. The Committee sought legal advice on what the term 'bee' meant in the legislation.

6.13. The advice noted that there are no statutory indicators to suggest that the term 'bee' should be limited to particular species and that there is no definition of 'bee' in the Act. Therefore, the normal and ordinary meaning of the word bee(s) should apply and the term 'bees' in the regulation should be taken to mean all bees and not be limited to honey bees or managed bees.

6.14. Therefore, the Committee have decided that the term bees in this decision and the subsequent controls will refer to all bee species (Apidae) and includes both wild and managed bees.

Substances covered the modified reassessment

6.15. This reassessment covers substances approved under any of the 15 approvals for plant protection products containing acephate, dimethoate, methamidophos, methomyl or oxamyl, which are listed in Table 1 below. This decision does not, and cannot, cover other substances containing these active ingredients or other substances that may impact bee health, such as neonicotinoid insecticides.

Table 1: Substances covered by this reassessment decision

Active ingredient	Approval number	Name of the substance on the public register*
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

Active ingredient	Approval number	Name of the substance on the public register*
Acephate	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
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
Methamidophos	HSR000203	Soluble concentrate containing 600 g/litre methamidophos (Substance B)
	HSR000226	Soluble concentrate containing 600 g/litre methamidophos (Substance A)
Methomyl	HSR000584	Soluble concentrate containing 200 g/litre methomyl
	HSR007761	ArmourCrop Insecticide
Oxamyl	HSR000791	Soluble concentrate containing 240 g/litre oxamyl

* This may differ from the commercial names of the product/s covered by each approval

7. Application and E&R report

7.1. The staff reviewed information on these substances held by the EPA, the information provided by submitters and that identified in a search of the scientific literature. This information was used to conduct a risk assessment which was presented to the Committee in the E&R Report, and which is available on the EPA website.

7.2. The primary purpose of the E&R report is to summarise the information available for the Committee, highlight the potential risks and propose possible measures to mitigate those risks.

8. Hearing and submissions

Applicant's summary of the application and the staff evaluation

8.1. The applicant was represented by the staff of the EPA, who presented the application and the outcomes of the E&R report to the Committee.

8.2. The staff introduced the proposed changes to the controls and the scope of the application; they described the history of the approvals for the substances covered by the approval, including the full OPC reassessment (APP201045) and the timeline for this reassessment. The staff also summarised and commented on the key issues raised in the submissions received and they summarised the content of the E&R report.

8.3. In describing the information available for each active ingredient the staff noted that most of the available information was not new research, but that it had not been considered by the Decision-Making Committee for APP201045. In response to questions from the Committee the staff acknowledged that, although the amount and quality of information was not ideal, (due to the age of the studies, methodologies used, or dissimilarity to current use patterns) it was the only and best information available. The staff also noted that there may be relevant unpublished studies and that industry (users, importers and manufacturers) were invited to provide additional information via the submission process.

8.4. In response to questions from the Committee, the staff responded that the key criteria for determining the non-contact periods was the time required to achieve normal mortality, not zero mortality, as suggested by some submitters. Normal mortality for honey bees is ~10-20% and is based on the mortality of bees in the control hive/s.

8.5. The staff also noted in response to questions that the original non-contact periods were carried over from previous legislation when the HSNO Act was established.

Summary of submissions – submitters heard in person

8.6. Seventeen submissions were received and eight submitters or groups of submitters provided oral submissions to the Committee at the hearing.

8.7. The Committee has reviewed the written submissions, the staff responses to the submissions in the E&R report and the presentations by the submitters at the hearing, and information received from submitters after the formal hearing but before the closure of the proceedings.

8.8. The Committee notes that some of the matters raised by the submitters are beyond the scope of this application, but where appropriate these matters have been included in the recommendations.

8.9. The key points from the submissions are noted in the following paragraphs, to summarise the main themes in the submissions, questions were raised around whether: the grounds for reassessment were valid; which bee species were covered by the proposed control; and the matter in which the application of the precautionary principle is applied in the Committee's decision making. The Committee has considered these matters and addressed them in other parts of this decision.

8.10. Market Access Solutionz presented on behalf of a number of horticultural interests. The lemon, strawberry and greenhouse tomato industries raised significant concerns about the practicality of the non-contact periods for their industries and the economic impacts that not being able to use the substance during non-contact periods would have. The submitters noted that the proposed controls would effectively ban the use of these substances on these crops. The submitters also presented information about the importance of the relevant organophosphates to their industries, the close relationships they have with local beekeepers and lack of reported adverse effects on bees.

8.11. Rick Curtis for the New Zealand Citrus Growers Association noted that acephate is vital for treating citrus flower moth *(Prays citri)*. The larva of this moth typically attacks the flowers of citrus trees. At

low flowering times it will also attack the fruit resulting in rindspots on the skin of the fruit. More than three spots on a fruit makes it unable to be sold to export markets and more than five spots makes it unable to be sold to domestic markets. Citrus flower moth is particularly difficult to control because it lives inside the flowers so is protected from most contact insecticides, except acephate.

8.12. Geoff Langford and Peter McIntyre for Strawberry Growers New Zealand noted that methomyl is critical for managing chewing and sucking insects which can damage fruit and stunt plant growth, thereby reducing yields. They also highlighted that methomyl is important for managing secondary fungal infections in fruit and ensuring the fruit is pest-free for export. The growers noted that there is currently no effective alternative for use on strawberries.

8.13. Both strawberry and lemon growers noted that bees are not required to pollinate these crops and that no negative impacts on local bee populations have been reported as a result of growers using these substances, despite representatives noting that bee hives are kept in close proximity to their crops.

8.14. Ben Smith from Tomatoes New Zealand reported that methomyl and oxamyl are essential for controlling white fly in commercial greenhouses and play a key part in their pest resistance management strategies. Good pest resistance management requires that several pest management tools are used interchangeably rather than relying on a single tool.

8.1. Mr Smith told the Committee that greenhouse tomatoes are managed so that plants are in flower for most (40+ weeks) of the year during which they must be pollinated continuously to produce fruit. Pollination is achieved through the use of bumble bees, reared commercially and purchased by growers. Therefore, for greenhouse tomatoes, the insect pollinator is owned by the grower rather than a beekeeper and honeybees and other insect pollinators are excluded from greenhouses.

8.2. Mr Smith further noted that European bumble bee breeders advise removing bumble bees from the greenhouses for 72 hours after spraying methomyl. However, 72 hours without pollination can affect the quality and quantity of fruit, so excluding bees for 24 hours after spraying is considered normal practice in New Zealand. When oxamyl is applied via the drip line irrigation system the good practice recommendation is that bumble bee hives are closed during application. These practices have been found to be sufficient to prevent adverse effects on bumble bees.

8.3. In conclusion, the various horticulture sector representatives stated that the proposed controls were impractical and unnecessary for use on strawberries, lemons and in the greenhouse situation.

8.4. Dr Oliver Sutherland, representing Ngāi Tahū, stated that the level of information used to set the non-contact periods was inadequate because the field trials cited had used lower application rates than are currently used in New Zealand and did not continue for long enough to justify the non-contact periods set. Dr Sutherland appealed to the Committee to apply the precautionary principle and set all of the non-contact periods to the maximum 10 days allowed by the regulations.

8.5. Dr Sutherland also noted that no information was presented about the impacts of these substances on native bee species and objected to the statement in the application form that the proposed non-contact periods will aid kaitiaki by protecting wild bees.

Submitters heard via teleconference

8.6. Malibu Hamilton (Clean Earth), Vera van der Voorden, Nora van der Voorden, Joan Haveman Paul Haveman, Don McLeod (National Beekeepers Association) and Frank Visser (Key Industries Limited), spoke to their submission at the hearing via telephone conference.

8.7. Mr Hamilton stated that they were concerned that the proposed controls were less stringent than those that were in place before the OPC reassessment (APP201045). He noted that there was little known about the 30+ species of bee that were not used for crop pollination and was concerned about the absence of monitoring that he believed would be required to ensure that controls protected these non-commercial bee populations. He expressed a lack of confidence the proposed controls would achieve their goal of protecting bees (commercial and non-commercial).

8.8. Vera van der Voorden discussed the value of bees as pollinators and stated that more needs to be done to protect bees, specifically that the proposed controls were not stringent enough to protect bees. She noted that a key issue was the knowledge of the applicators and the care taken to apply these substances appropriately, and she said she had found a high degree of carelessness among growers and a disregard for withholding periods from her experience working in the horticultural industry.

8.9. Nora van der Voorden noted that at certain times of the year large numbers of dead and dying bees (honey and bumble bees) can be found in the Waikato Region where she lives and this is generally attributed to the careless use of pesticides in surrounding agricultural areas. She considered that the proposed controls were not stringent enough, particularly the suggestion that spraying at night would protect bees.

8.10. Mrs Havemann provided general information about the impact of pesticides on bees internationally and raised concerns about the impact of pesticides on bee populations and vulnerable human populations, and regular non-compliance with label statements. She recommended that the EPA stop using a risk assessment based approach and phase out toxic pesticides in favour of non-toxic, low toxicity pesticides or organic approaches.

8.11. Professor Havemann, provided information about the importance of bees and pollination services to human food production and the impact that pesticides and climate change have or are expected to have on bee populations in the future. He stated that the Committee should apply the precautionary principle and ban the use of organophosphate, carbamate and neonicotinoid pesticides because there is no certainty that the proposed non-contact periods will protect bee populations. Professor Havemann advocated that the Government promote organic agricultural systems, undertake a

national pollinator census and health assessment, review all contemporary literature on organophosphate pesticides and evaluate alternatives to pesticide use.

8.12. Frank Visser, from Key Industries Limited, supported the proposal to add non-contact periods to these substances, and stated that the impacts of insecticides that translocate to the nectaries of plants should not be discounted. He also asked to committee to extend its review to neonicotinoid insecticides and the use of methomyl as an ant repellent.

Submitters not wishing to be heard

8.13. Written submissions were received from six individuals and organisations who indicated that they did not wish to be heard at the hearing

8.14. Yvonne Curtis stated that the EPA should be conservative in its decisions and ensure that pesticides are proved safe before they are approved. She also asked the Committee to ban the use of neonicotinoids in New Zealand.

8.15. Lori Anderson, from Ngati Huarere Ki Whangapoua, opposed the application because the substances are listed as nerve agents (organophosphates are neurotoxic) which are toxic to humans, wildlife and bees. She noted that the use of these substances may impact the ability of Māori to fulfil their duty as kaitiaki.

8.16. James Hadlow from Stepping Stones Nursery stated that he supported the application because bees are important for food production.

8.17. Noel Blackwell from Rural Contractors New Zealand stated that he supported the application and measures that promote bee health. Rural Contractors New Zealand operates an accreditation programme for chemical applicators. He stated that if there was a problem with the application of these pesticides that their use should be restricted to registered chemical applicators.

8.18. Dr John Liddle, Chief Executive of the Nursery and Garden Industry New Zealand (NGINZ), stated that NGINZ supported the proposal to reinstate non-contact periods and considered that this was unlikely to have a significant effect on the nursery and garden sector, because these requirements have previously been applied to these substances. He also believed that NGINZ's members were well aware of the previous requirements for non-contact periods specified on the labels.

8.19. Ann Thompson from Federated Farmers of New Zealand stated that Federated Farmers supported the re-introduction of non-contact periods. She noted that similar requirements existed before the reassessment of OPC (APP202145) and it was important to apply these pesticides well before flowering because serious poisoning at the start of the pollination and nectar season could have serious consequences for hive mortality. She also advocated for clear labelling requirements to inform users of the non-contact periods.

8.20. Greg Mitchell from Du Pont stated that Du Pont did not support the non-contact periods in their current form (i.e. as proposed in the application form). He said they did not support the off label use

of their substances (Lannate L containing methomyl and Vydate L containing oxamyl). It was their understanding that only strawberries would be affected by the proposed changes to methomyl and the changes to oxamyl would have no effect because all uses except in farrow application to seedling carrots are about to be withdrawn.

8.21. Mr Mitchell advocated that, rather than the proposed non-contact periods, beehives be removed from in and around fields before spraying and are not reintroduced for three days. Du Pont provided two studies to the Committee, in confidence, to support their proposal.

Applicant's right of reply

8.22. At the end of the hearing, the EPA staff presented the applicant's 'right of reply'. The staff commented on the alternative controls proposed by the submitters and stressed that it may not be legally robust to set crop-specific controls, as proposed by some submitters. They noted that legal advice received during the OPC reassessment (APP201045) recommended against doing this.

8.23. The staff also noted that the practicalities of the proposal to apply a notification zone should be considered carefully and that they were not aware of any information that could be used to determine the appropriate size of such a notification zone.

Post hearing

8.24. The hearing was adjourned on 17 February 2015 to allow further information to be received by the Committee. The Committee requested the following information:

- The submitters who were heard by teleconference were asked to provide written transcripts of their oral submissions.
- Astrya Life Sciences were asked to formally comment on the staff's assessment of their study, which was presented in the E&R report.
- The staff were asked to provide a written response to Arystra Life Sciences' feedback.
- Don McLeod from the National Beekeepers Association was asked to review the Market Access Solutionz submission and to provide written comments.

This information was made available to the submitters.

8.25. The Committee also received legal opinions form the EPA legal team on the:

- definition of the term 'bee'
- role of the EPA staff when the Chief Executive of the EPA is the applicant
- validity of the grounds decision.
- application of the precautionary principle; and
- setting of crop-specific controls that had been provided to the original Decision-Making Committee for APP201045.

8.26. The legal opinion on the definition a bee was circulated to the submitters, while the other legal advice has been incorporated into this decision where applicable.

8.27. The hearing was formally closed on 16 March 2015.

8.28. On 7 April the staff provided the Committee with a memo outlining the legal position on setting crop-specific controls that was determined during the full OPC reassessment (APP201045).

9. Consideration of matters applicable to all substances

9.1. The Committee reviewed all of the information presented to it in written and oral form, and used it to inform its decision on this application.

9.2. The Committee took a range of factors into consideration during its deliberation on this application, including the risk of the substances to bees; how, when and why the substances are used; the social, cultural and economic implications of making the proposed change, the alternative proposals or retaining the status quo. Some of the matters considered related to all of the active ingredients, while others related only to specific active ingredients.

9.3. Matters relating to all of the active ingredients are covered below. Matters relating to specific active ingredients or which form part of the reasoning for the decision for that active ingredient are discussed in section 10 under the heading for the relevant active ingredient. A summary of the controls is presented in Table 3 in section 12.

Application of the precautionary principle

9.4. Section 7 of the Act requires the Committee to take into account the need for caution when deciding how to manage adverse effects when there is scientific and/or technical uncertainty about those effects i.e. to apply the precautionary principle.

9.5. The Committee acknowledges that there is some uncertainty or inherent variability in the magnitude and/or likelihood of both the potential adverse and positive effects of the proposed change including non-contact periods.

9.6. This uncertainty is primarily addressed (and the precautionary principle applied) by the Committee's application of the HSNO decision making methodology (The Methodology) as described in the Hazardous Substances and New Organisms (Methodology) Order 1998.

9.7. The Methodology describes the approach the Committee should take when dealing with uncertainty, including: determining the materiality and significance of the uncertainty to the application; seeking to clarify and resolve uncertainty; and exercising caution when determining how to manage the adverse effects.

9.8. The Committee notes that the precautionary approach is intended, and is applied, as the need to take a conservative approach where the level of information may be limited. The precautionary approach is not intended to justify doing nothing or allowing nothing when there is some uncertainty. The proper application of the precautionary approach is particularly important for reassessments of older chemicals where there is a history of use but for which a complete data set may not be available or where scientific techniques may have improved since the available data were produced.

9.9. The staff advised that the precautionary approach is also reflected in the scientific risk assessment methods. For example, it is standard practice in toxicology and ecotoxicology to include uncertainty factors, which make an assessment more conservative, when assessing the risks to one species based on data from another. This approach is used in the EPA's native species assessment to provide additional caution when there are little or no data to indicate that the effects of substances on native species are likely to be similar to those on test species.

9.10. The Committee was presented with conflicting views on how the precautionary approach ought to be applied in this application. On the one hand some submitters considered that the degree of uncertainty relating to impacts on bees, particularly native bees, indicated a need to apply conservative non-contact periods. On the other hand, some submitters considered that uncertainty about the impacts on bees raised questions about the necessity for and the effectiveness of the proposed non-contact periods, especially in the light of the potential negative economic impacts of applying these periods particularly in relation to some crops (i.e. lemons and strawberries) and in some situations (i.e. greenhouses).

Amount of information available to the Decision-Making Committee

9.11. The Committee assessed the quality and quantity of information available in accordance with the methodology. The staff summary of the studies used to determine the non-contact periods was presented to the Committee in the E& R report. Specific comments on the information available for each active ingredient are presented in section 10.

9.12. The Committee noted that the quality and quantity of information available was less than what it would have expected to see if this application had been for a new substance. After careful consideration the Committee accepted that the amount and type of information available for old active ingredients is generally more limited and/or based on research conducted using methods or protocols that have since been superseded. The Committee is aware that some studies that are routinely conducted today may not have been performed when these substances were first registered, or in the intervening years. With all the products being manufactured off shore New Zealand is very reliant on overseas data when undertaking assessments.

9.13. The Committee noted that the staff had completed a full review of the available literature and that two submitters supplied three further unpublished studies which the Committee also considered. Subsequently the Committee considered that a further search of the published literature was unlikely to yield significant additional studies and that the information provided was the best likely to be available at this point in time.

9.14. The Committee therefore considered that it had sufficient information to assess the application.

General assessment of the risks

Matters relating to the risks to bees

9.15. Acephate, dimethoate, methamidophos, methomyl and oxamyl are broad-spectrum insecticides. Therefore bees could be adversely affected by contact with these substances if the substances are applied to plants where bees are foraging.

9.16. Organophosphates and carbamates affect the nervous systems of insects, which can result in death or sub-lethal effects that could, in honeybees, have flow-on effects for hive health, such as reduced food resources from less foraging. Some of the sub-lethal effects observed in honeybee studies used to assess these substances included: decreased flight intensity, reduced foraging activity, coordination problems, disorientated or weakened bees and abnormal cleaning behaviour.

9.17. Bees are communal animals so the aim of bee protection measures is not just to protect individual bees but to ensure the health and longevity of the hive community. This lends weight to the consideration of sub-lethal effects that may result in individual bees contributing food to the hive community. If enough bees are affected in this way the productivity or survival of the hive could be affected.

9.18. For bees to be affected by these substances, they must be exposed to them. Exposure could occur during or immediately after spraying when the spray is still wet or for several days after spraying via dried but still active spray residues on leaves or flowers. Non-contact periods are intended to prevent, or significantly reduce, bees' exposure to pesticides that can impact on bees even when the residues are no longer wet.

Risks of the change proposed by the application

9.19. The risks of applying non-contact periods are primarily economic, and relate to specific horticultural industries which may be left without effective tools to manage key pests because non-contact periods will mean that the pesticide is not able to be used in any practical sense.

9.20. The key concerns from the submitters related to a lack of alternative products, a potential decrease in fruit (strawberry and lemon) quality and the impact this would have on domestic and export earnings. In relation to export products, the growers would not be able to meet the biosecurity requirements of export partners which would mean crops could not be exported at all.

Risks of non-compliance

9.21. Prior to the reassessment of all OPCs in application APP201045, non-contact periods were applied to these substances but Market Access Solutionz reported that there was little or no compliance with those requirements. This was primarily due to a lack of knowledge that the non-contact periods existed because in some cases the non-contact periods were not stated on the product labels. The

EPA staff advised that they had undertaken a review of the old labels[1] and use instructions[2] that were available for the products covered by this reassessment, showed that some included the non-contact period information but others did not.

9.22. The Committee is cognisant of the fact that reinstating non-contact periods could mean that the non-contact periods are ignored because growers see them as impractical and unnecessary.

Risk of not being protective enough

9.23. Ngāi Tahu submitted that the level of information available was too limited to set non-contact periods any less than the maximum 10 days permitted by the Act, and that the proposed non-contact periods were not protective enough. Ngāi Tahu urged the Committee to apply the precautionary principle and set non-contact periods on all substances at the maximum 10 days.

Cultural risk

9.24. Ngāi Tahu submitted that the lack of scientific information about the effects of these substances on native bees, or how native bees compare to honeybees, means the risks to native bees are uncertain and may be higher than expected. Ngāi Tahu further submitted that if native bees were at greater risk, then the lack of protection of them could result Māori not being in a position to fulfil their role as kaitiaki. This reinforced Ngāi Tahu's submission that the most conservative non-contact periods (10 days) be applied.

Risks of the st

atus quo

9.25. In considering the status quo (e.g. no non-contact periods), the Committee considered whether bees would be at risk from pesticide residues on plants that have recently been sprayed even after the spray had dried. There is no debate that decreases in honey bee populations would have flow-on effects on honey production and pollination services for both horticulture and other primary sectors.

General assessment of the benefits

Benefits of bee health and pollination services

9.26. Honey and bumble bees are important pollinators for a wide range of native, ornamental, commercially grown plants. Less is known about native bees as pollinators, particularly in the commercial sector. Honey is an important commodity for New Zealand. Honey exports are reported to be worth about $120 million per year[3].

[1] ACVM register, https://eatsafe.nzfsa.govt.nz/web/public/acvm-register labels dated before June 2013

[2] New Zealand Novachem Agrichemical Manual (2010) Editor Stuart Young, AgriMedia, Christchurch, New Zealand.

[3] http://www.beehive.govt.nz/sites/all/files/FAQs.pdf

Benefits of the change proposed by the application

9.27. The proposed change will reduce the likelihood that bees will be exposed to acephate, dimethoate, methamidophos, methomyl or oxamyl at levels that could result in an adverse effect.

9.28. Applying non-contact periods to these substances will meet the intention of the current E3 control which is to restrict the use of a substance so that it is not used where it poses a high risk to beneficial insects such as honeybees, by restricting the substances' use in areas where bees are foraging or on specific plants which are likely to be visited by bees.

9.29. Applying non-contact periods to these substances will protect bee health which could have flow-on effects for honey production and effective pollination services for the horticultural sector.

Alternative proposals to the controls proposed by the applicant

9.30. Market Access Solutionz proposed an alternative approach to ensure the protection of bees and maintain the use of these substances in key sectors, namely for use on lemons, strawberries and in greenhouses.

9.31. Rather than having a non-contact period applying to the substances, the submitters proposed that growers should be required to notify all beekeepers in the area before they apply acephate (for lemons) and methomyl (for strawberries) so beekeepers can choose to remove their hives for the 7 or 8 day period after spraying.

9.32. The Committee noted that this would provide a good 'middle ground' practical solution. However, the EPA staff pointed out that that such a control has some challenges particularly that it is always difficult in practice to ensure that notification is comprehensive. Honeybees are known to travel considerable distances to forage so the spatial boundaries of notification would be difficult to ascertain. In addition, such a requirement may protect commercial honeybees from exposure to these substances, but it would not protect wild or native bees, so would only be partially effective in achieving the protection goal of the control.

9.33. The Committee noted that there were no data on the importance of lemons, strawberries or greenhouse crops for the maintenance of populations of wild bees, native or exotic, in New Zealand.

9.34. The Committee considered all the information received on this proposal and thanks Market Access Solutionz's pragmatic and reasonable approach in this matter. However, due to the difficulties noted the Committee decided not to proceed with this approach.

10.Consideration of individual substances

Consideration of Acephate

Background

10.1. Acephate is used to control grass grub beetles, aphids, caterpillars, citrus flower moth in fruit, vegetables, citrus and ornamentals.

10.2. There are currently five approvals for products containing acephate for use on crops.

- 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

10.3. Only two commercial products containing acephate are currently registered with ACVM[4], both of which are approved under HSNO approval HSR000155.

10.4. Prior to the reassessment of all OPCs (APP201045) a 7-day non-contact period applied to products containing acephate. There is currently no non-contact period set for these substances. The Applicant proposed reinstating the 7-day non-contact period and requiring this information to be on the label.

The proposed controls

10.5. The variation to the E3 and label statement controls proposed by the staff in the E & R report were:

E3 control

Subclause (1)(b)(ii) and clause (2) of regulation 49 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 are replaced by the following subclause:

(b) the plant or tree is likely to flower after application of the substance within 7 days.

Label statement R-9 control

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—

[4] The Agricultural Compounds and Veterinary Medicines Group of the Ministry of Primary Industries; all pesticides applied to food crops must be registered by ACVM before they can be sold in New Zealand. If there are not registered products for an approval it is assumed that that approval is currently unused.

(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 7 days.

Assessment of the level of information available

10.6. The Committee has reviewed the data and study summaries provided by the staff, the submissions, and a study report provided by Market Access Solutionz.

10.7. Three aged residue and five degradation studies were used to support the proposed non-contact period for acephate. These are summarised in the E&R report.

10.8. With the caveats mentioned above about the nature and age of the studies, on balance, the Committee is satisfied that the level of information is sufficient to proceed with consideration of the proposed change.

Risks, costs and benefits of the proposed change to the lemon growing industry

10.9. Acephate is the principal tool for treating citrus flower moth, which causes rindspotting on lemons. Rindspots affect the appearance and quality of the fruit, and can lead to fruit being unable to be sold as fresh produce on the domestic or export market.

10.10. Market Access Solutionz estimates that not being able to use acephate to control citrus flower moth would cost the lemon industry approximately $10.6 million per year in lost earnings because they would only be able sell to low value markets (such as for juicing); such losses could make some lemon growing operations uneconomical. They also state that it would be nearly impossible to meet the high quality requirements for export fruit without using acephate to control citrus flower moth and prevent rindspotting. Export earnings account for $2.2 million for the potential $10.6 million in lost earnings.

10.11. The submitter estimates that imposing a non-contact period would effectively remove acephate from their industry because lemon trees flower continuously. This would make it uneconomical to grow lemons resulting in the removal of a significant number of lemon orchards with flow-on effects for people or businesses employed by the lemon industry such as those involved in pack house activities.

10.12. The Committee accepted that the proposed non-contact periods would result in non-negligible economic risks to lemon growers.

Consideration of alternative controls

10.13. Market Access Solutionz proposed the alternative control described above (in section 9.30-9.33) but the Committee decided that for practical reasons such a control should not be imposed.

10.14. It is the Committee's view that the use of acephate on lemons be exempt from the specified non-contact period applicable to other crops. This is on the basis that the use of acephate on lemons poses a lower risk than its use on crops that are pollinated with honeybees, and the significant non-negligible economic risks posed by applying the non-contact periods to this crop.

Committee's revised control

10.15. The proposed variation to the E3 and label statement controls are:

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, except lemon trees, that is likely to be visited by bees if the plant or tree is in open flower or part bloom; or

(c) to any plant or tree, except lemon trees, that is likely to be visited by bees if the plant or tree is likely to flower after application within 7 days of the substance being applied.

Label statement R-9 control

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 (except lemons) is likely to flower within 7 days after application of the substance.*

Review of the risks, costs and benefits of the revised control

10.16. The Committee considers that applying non-contact periods to substances containing acephate is likely to benefit bee health, which will have subsequent economic benefits for pollination services, the horticulture industry and honey production. However, non-contact periods would also pose non-negligible economic risks to the lemon growing industry by hindering the effective control of citrus flower moth. Therefore the Committee has applied the non-contact periods with an exemption for lemons.

10.17. The Committee notes that by applying an exemption, full risk reduction will not be realised, however, given the size of the New Zealand lemon crop, the fact that honey bees are not reliant on lemon trees for food, that lemons do not require honeybees for pollination, and that lemon orchards are not expected to be New Zealand's sole habitats for wild or native bees, the Committee considers that the loss of risk reduction will be minor. The Committee also considers that the economic benefits of retaining an important pest management tool for the lemon industry outweigh the residual risk of exempting lemons from the non-contact period.

10.18. The Committee stresses that the exemption only applies to parts 1(b)(i) and 1(b)(ii) of the control and that part 1(a) of the control still prohibits acephate being applied if bees are foraging in the area and the substance is in a form in which bees are likely to be exposed to it.

Review cost effectiveness of the revised control

10.19. The Committee considers that the application of controls with the identified exemption is the most cost effective way to manage the environmental risks while being cognisant of the economic risks to the lemon growing industry of applying the proposed controls.

Committee Decision

10.20. The Committee has considered the risks, costs, benefits and cost-effectiveness of the proposed controls and considers that the variation to the E3 control is more effective for managing the risks, use and management of the substance than the current control. It considers that applying a crop-specific exemption will provide the appropriate balance between the needs of the lemon growing industry and the broader environmental protection needs.

10.21. They also consider that requiring a label statement is more likely to achieve the purpose of the control, i.e. to protect bees, than not requiring such information on the label.

10.22. Consequently the Committee's revised controls (E3 and labelling) are applied to the approvals for acephate (HSR000154, HSR000155, HSR000156, HSR000157, and HSR000158).

Consideration of Dimethoate

10.23. Dimethoate is used to control grass grub beetles, aphids, thrips, whitefly, leaf miners, springtails and mealy bug in fruit, vegetables, pasture, fodder crops and ornamentals.

10.24. There are currently five approvals for products containing acephate for use on crops.

- 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

10.25. Three commercial products containing dimethoate are currently registered with ACVM; they are approved under HSNO approvals HSR000129, HSR000188 and HSR00965.

10.26. Prior to the reassessment of all OPCs (APP201045) a 7-day non-contact period applied to products containing dimethoate. There is currently no non-contact period on products containing this dimethoate. The staff proposed reinstating the 7-day non-contact period and requiring this information to be on the label.

10.27. Growers' groups have indicated that dimethoate is not an important active ingredient to them and the addition of non-contact periods is not likely to have an impact on industry. No other submitters raised any issues with regard to dimethoate.

The Applicant's proposed controls

10.28. The proposed variation to the E3 and label statement controls are:

E3 control

Subclause (1)(b)(ii) and clause (2) of regulation 49 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 are replaced by the following subclause:

the plant or tree is likely to flower after application of the substance within 7 days.

Label statement R-9 control

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 7 days.

Assessment of the level of information available

10.29. The Committee has reviewed the data and study summaries provided by the staff and the information provided in submissions.

10.30. Dimethoate is commonly used as a toxic reference in standard good laboratory practice (GLP) studies to evaluate the effects of other substances. Several such studies, received as part of an application for a new active ingredient, were used to support the proposed non-contact period.

10.31. Six semi-field tunnel tests and four degradation studies were used to support the proposed non-contact period for dimethoate.

10.32. The Committee is satisfied that the level of information is sufficient to consider the proposed change.

Assessment of the risks, costs, benefits and alternative controls

10.33. The horticulture industry did not cite any concerns or economic risks associated with the proposed controls for dimethoate. They did however indicate that any non-contact period or similar controls should be stated on the product label to assist growers to comply with the controls.

10.34. The Committee considers that the proposed control is likely to benefit bee health, which will have subsequent economic benefits for pollination services for the horticulture industry and honey production, and that no non-negligible economic risks were identified.

10.35. Subsequently the Committee considers that the risks of changing the current control to the proposed control are negligible and that there are non-negligible benefits to making this change. They also consider that this is the most cost-effective way to manage the risks to bees at this time.

Committee Decision

10.36. The Committee has considered the risks, costs, benefits and cost-effectiveness of the proposed controls and consider that the variation to the E3 control is more effective for managing the risks, use and management of the substance than the current control. It also considers that requiring a label statement is more likely to achieve the purpose of the control, i.e. to protect bees, than not requiring such information on the label. Therefore the Applicant's proposed controls (E3 and labelling) are applied to the approvals for dimethoate (HSR000188, HSR000191, HSR00019, HSR000965, and HSR100129).

Consideration of Methamidophos

Background

10.37. Methamidophos is used to controls aphids and caterpillars in fruit, vegetable and maize crops.

10.38. There are currently two approvals for products containing methamidophos for use on crops.

- HSR000203 - *Soluble concentrate containing 600 g/litre methamidophos (Substance B)*
- HSR000226 - *Soluble concentrate containing 600 g/litre methamidophos (Substance A)*.

10.39. Two commercial products containing methamidophos are currently registered with ACVM; both are approved under approval HSR000226.

10.40. Prior to the reassessment of all OPCs (APP201045) a 7-day non-contact period was applied to products containing methamidophos. There is currently no non-contact period on substances containing methamidophos. The staff proposed retaining the no non-contact period but restricting the application of products containing methamidophos until after bees have finished foraging for the day and require this information to be on the label.

The proposed controls

10.41. The proposed variation to the E3 and label statement controls are:

E3 control

Regulation 49 subclauses (1) and (2) are deleted and replaced by:

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.

Label statement R-9 control

(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)

Assessment of the level of information available

10.42. The staff reviewed information from the European Commission Health & Consumer Protection Directorate-General[5] and provided a summary to the Committee in the E&R report. This information included summaries of cage and field studies presented in the European Commission Health & Consumer Protection Directorate-General report. The EPA staff were not able to review of the original studies because these were not available to them.

10.43. The summary showed that, whilst methamidophos is ecotoxic to bees immediately after application, the toxicity of methamidophos rapidly decreases post application, and bee deaths associated with methamidophos are limited to the first 24 hours after application.

10.44. The Committee notes that the level of information is not as robust as what they would expect for a new active ingredient. However the Committee accept that recent information on older active ingredients can be limited. Given the source of the information, the Committee is satisfied with the quality and level of information available in the European Commission's summaries and considers that the level of information is acceptable to support consideration of the proposed control.

[5] 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

Assessment of the risks, costs, benefits and alternative controls

10.45. The horticulture industry did not cite any concerns or economic risks associated with the proposed controls for methamidophos. They did however indicate that any non-contact period or similar controls should be stated on the product label to assist growers to comply with the controls.

10.46. One submitter proposed adding 5-day non-contact periods to products containing methamidophos because methamidophos as a reported degradation half-life (DT_{50}) of 4.6-11.9 days. However, the Committee note that the key parameter is how long it is toxic to bees, not simply how long it is present in the environment. Half-life is a measure of persistence not toxicity. The study presented in the application indicates that methamidophos is only toxic to bees immediately after application, and therefore extended non-contact periods are not supported by the information available.

10.47. The Committee considers that the proposed control is likely to benefit bee health, which will have subsequent economic benefits for pollination services for the horticulture industry and honey production, and is not expected to results in non-negligible social, economic or cultural risks.

10.48. Subsequently the Committee considers that the risks of changing the current control to the proposed control are negligible and that there are non-negligible benefits.

Review cost effectiveness of the revised control

10.49. The Committee considers that the application of controls is the most cost effective way to manage the risks posed by the substance.

Committee Decision

10.50. The Committee has considered the risks, costs, benefits and cost-effectiveness of the proposed controls and consider that the variation to the E3 control is more effective for managing the risks, use and management of the substance than the current control. It also considers that requiring a label statement is more likely to achieve the purpose of the control, i.e. to protect bees, than not requiring such information on the label. Therefore the applicant's proposed control is applied to approvals containing methamidophos (HSR000230 and HSR000226).

Consideration of Methomyl

Background

10.51. Methomyl is used to control aphids, thrips and caterpillars in fruit, vegetable and cereal crops.

10.52. There are currently two approvals for products containing methamidophos for use on crops.

- *HSR000584 - Soluble concentrate containing 200 g/litre methomyl*
- *HSR000226 - ArmourCrop Insecticide (Methomyl)*

10.53. Two commercial products containing methomyl are currently registered with ACVM; both are approved under HSNO approval HSR000584.

10.54. Prior to the reassessment of all OPCs (APP201045) a 10-day non-contact period was applied to products containing methomyl. There is currently no non-contact period on substances containing methomyl. The staff proposed reinstating the non-contact period but reducing it to 8 days, and requiring this information to be on the label.

The applicant's proposed controls

10.55. The proposed variation to the E3 and label statement controls are:

E3 control

Subclause (1)(b)(ii) and clause (2) of regulation 49 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 are replaced by the following subclause:

the plant or tree is likely to flower after application of the substance within 8 days.

Label statement R-9 control

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 8 days.

Assessment of the level of information available

10.56. The Committee has reviewed data and study summaries provided by the staff and the information in the submissions.

10.57. A semi-field tunnel test, two semi-field cage tests, one degradation study and a review of data from the European Food Safety Authority Draft Assessment Report were used to support the proposed non-contact period on methomyl.

10.58. The Committee is satisfied that the level of information is sufficient to consider the proposed change.

Risks, costs and benefits of the proposed change to the strawberry growing industry

10.59. Methomyl is used in the strawberry industry to treat fruit before harvest in order to prevent insect damage and prevent insects being present on the harvested fruit, which is important for both the domestic and export fresh fruit markets. Methomyl is also used to prevent viruses and fungal infections, transmitted by insects, which can stunt the growth of the strawberry plants and have economic implications for growers.

10.60. Strawberry growers state that they do not have any effective alternative products to treat their crops before harvest. A key factor in this is that the methomyl has an established MRL and withholding period of 2 days, which makes it suitable for pre-harvest application; whereas potential alternatives have longer withholding periods so cannot be applied immediately before harvest.

10.61. Market Access Solutionz, representing the strawberry industry, estimate that the inability to use methomyl would result in a 40% decrease in the fresh strawberry crop in New Zealand and that the loss in quality and quantity would equate to a $20 million loss for the industry on the domestic market. In addition, the export strawberry market is worth $4.8 million per year and has been severely impacted in the past by pest interceptions on fruit, hence the need to apply insecticides before harvest.

10.62. Growers note that the proposed non-contact periods would effectively ban the use of methomyl on strawberries, which can flower continuously from around August to April, with fruit being harvested continuously every two days from late September until April. Growers submit that not being able to use methomyl would make it uneconomical to grow strawberries due to the reduction in quality and quantity of fruit, and the fact that it is not economical to grow solely for the processed food market.

10.63. In summary the proposed controls pose an economic risk to strawberry growers and may affect the export potential of the strawberry crop. Strawberry growers claim that applying methomyl to their crops poses a lower risk to bees than applying the same substances to other crops because bees are not used to pollinate strawberries and strawberries are not highly attractive to bees.

Risks, costs and benefits of the proposed change to the greenhouse growers

10.64. Methomyl is used in greenhouse crops to control a range of pests, primarily whitefly and tomato potato psyllid (TPP), which can directly damage the plant and transmit bacterial and fungal diseases that damage the fruit.

10.65. Growers note that greenhouse tomato crops are in production (i.e. flowering and fruiting) for approximately 10 months of the year and it is important to use a variety of active ingredients to effectively manage pest resistance to any particular active ingredient. Methomyl and oxamyl form an important part of grower's pest management and resistance management strategies. Matters relating to oxamyl are discussed in the next section.

10.66. Methomyl is particularly important for providing effective insect control up until harvest because it has a short withholding period. Growers claim that the proposed non-contact periods would severely restrict the use of products containing methomyl on greenhouse crops, which in turn could compromise current disease management programs.

10.67. Greenhouse tomatoes are routinely pollinated by bumble bees, which are kept for this purpose. Despite the fact that the proposed control is intended to protect bees and the services provided by bees, growers predict that the proposed non-contact periods would have a negative impact on pollination services for greenhouse tomatoes. Greenhouse tomatoes are constantly being pollinated

by bumble bees and harvested every few days. Gaps in pollination would affect the quality and quantity of fruit harvested which in turn would affect the economic viability of growing operations.

10.68. Unlike pollination in open fields, greenhouse growers own the bees that they use. Growers therefore feel that they should be able to accept the voluntary risks associated with the pesticides they use (i.e. by covering or removing the hives during spraying) and be able to optimise the impact on their bees, their needs for pollination services and pest management. If, for example, a grower's bees are adversely affected by the pesticides then the full cost of replacing the bees falls on the grower who applied the pesticide.

10.69. In addition, the greenhouse itself acts like a containment system in that other bees and insects are excluded to the extent practical. Therefore, the risk of adversely affecting native, wild or commercial honeybees is considered negligible

10.70. In summary greenhouse growers argue that the risk profile for bumble bees in greenhouses is different than for all bees in open fields and therefore the non-contact periods should not apply to pesticide use in greenhouses.

Committee's revised controls

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, except tomatoes grown in greenhouses and strawberries, that is likely to be visited by bees if the plant or tree is in open flower or part bloom; or

(c) to any plant or tree, except tomatoes grown in greenhouses and strawberries, that is likely to be visited by bees if the plant or tree is likely to flower after application within 8 days of the substance being applied.

Label statement R-9 control

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 (except strawberries and greenhouse tomatoes) is likely to flower within 8 days after application of the substance.

Review of the risks cost and benefits of the revised control

10.71. The Committee considers that applying non-contact periods to substances containing methomyl is likely to benefit bee health, which will have subsequent economic benefits for pollination services, the horticulture industry and honey production. However, non-contact periods would also pose non-negligible economic risks to the strawberry and greenhouse tomato industries by hindering the effective control of key pest species. Therefore the Committee has applied the non-contact periods with an exemption for strawberries and greenhouse use.

10.72. The Committee notes that by applying an exemption full risk reduction will not be realised, however given the size of the New Zealand strawberry crop and the fact that greenhouses provide a barrier to wild and honey bees the Committee considers that the risks to bees will be minor. The Committee also considers that the economic benefits of retaining an important pest management tool for these sectors of the horticulture industry outweigh the residual risk of exempting strawberries and greenhouse use from the non-contact period.

10.73. The Committee stresses that the exemption only applies to parts 1(b)(i) and 1(b)(ii) of the control and that part 1(a) of the control still prohibits methomyl being applied if bees are foraging in the area and the substance is in a form in which bees are likely to be exposed to it.

Review cost effectiveness of the revised control

10.74. The Committee considers that the application of controls with the identified exemptions is the most cost effective way to manage the environmental risks in balance with the economic risks to industry of applying the proposed controls.

Committee Decision

10.75. The Committee has considered the risks, costs, benefits and cost-effectiveness of the proposed controls and considers that the variation to the E3 control is more effective for managing the risks, use and management of the substance than the current control. It consider that applying a crop-specific exemption will provide a practical balance between the needs of the greenhouse and strawberry growing industries, and the broader needs to protect bees in the environment.

10.76. It also considers that requiring a label statement is more likely to achieve the purpose of the control, i.e. to protect bees, than not requiring such information on the label.

10.77. Consequently the Committee's revised controls (E3 and labelling) are applied to the approvals for methomyl (HSR000584 and HSR000226).

Consideration of Oxamyl

Background

10.78. Oxamyl is used to controls aphids and caterpillars in fruit and vegetable crops and on pasture.

10.79. There is currently one approval for a substance containing oxamyl, that is:

- HSR000791- Soluble concentrate containing 240 g/litre oxamyl

10.80. There is currently only one commercial product containing oxamyl currently registered with ACVM.

10.81. Prior to the reassessment of all OPCs (APP201045) a 10-day non-contact period was applied to products containing oxamyl. There is currently no non-contact period on products containing oxamyl. The staff have proposed reinstating the 10-day non-contact period and requiring this information to be on the label.

The controls proposed by the applicant

10.82. The proposed variation to the E3 and label statement controls are:

E3 control

Subclause (1)(b)(ii) and clause (2) of regulation 49 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 are replaced by the following subclause:

the plant or tree is likely to flower after application of the substance within 10 days.

Label statement R-9 control

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 10 days.

Assessment of the level of information available

10.83. The Committee has reviewed the data and study summaries provided by the staff and the submissions.

10.84. A review of the United States Environmental Protection Agency Interim Reregistration Eligibility Decision (IRED) and a comparison between the application rates typically used in the United States and New Zealand was used to support the proposed non-contact period.

10.85. The Committee is satisfied that the level of information is sufficient to consider the proposed change.

Risks, costs and benefits of the proposed change to the greenhouse growers

10.86. Oxamyl is used on greenhouse crops to control a range of pests primarily whitefly and tomato potato psyllid (TPP), which can directly damage the plant and transmit bacterial and fungal diseases that damage the fruit. Oxamyl can be applied as a foliar spray, but is also added to the automatic drip-feed irrigation systems in greenhouses. However, the staff note that the use of oxamyl on tomatoes and in irrigation systems are off-label uses i.e. these uses have not been assessed and approved by the ACVM Group of MPI and therefore cannot legally be listed on the label or promoted to users.

10.87. In the greenhouse tomato industry oxamyl is used in integrated pest management (IPM) programs for whitefly. The IPM program uses the biological control agent *Encarsia formosa*, which is a parasite of whitefly, to control whitefly populations in greenhouses. When the populations of whitefly are high oxamyl is delivered via the irrigation system in the greenhouse to reduce the population of whitefly and allow the biological control to start working effectively (i.e. to give it a 'helping hand').

10.88. Growers claim that the proposed non-contact periods would effectively ban the use of oxamyl on greenhouse tomato crops (which flower continuously), which in turn could compromise current pest management programs and the economic returns from crops.

10.89. Applying non-contact periods to oxamyl would also affect the pollination to greenhouse tomatoes, in the same way as described above (10.67) for methomyl; which could impact the quality and quantity of fruit produced.

10.90. As with methomyl the risks posed to commercially grown bumble bees, which are part of the greenhouse agricultural system, from the use of oxamyl in the greenhouse is different from the risk posed by broad acre spraying outdoors which may affect wild bees and honey bees. Therefore the Committee considers that non-contact periods should not apply to pesticide use in greenhouses.

Consideration of alternative controls

10.91. The Committee notes the arguments presented by industry above and initially considered exempting greenhouse tomato crops from the non-contact period in a similar way to the exemptions applied for lemons and strawberries above. However, the Committee notes that use on tomatoes and in greenhouses are not on the label of the only commercial product containing oxamyl. This means that these uses have not been approved by the ACVM Group of the Ministry of Primary industries. It is not unlawful for growers to use a product in a way that is not on the label but it is unlawful to promote off-label uses. The Committee notes that if they exempted greenhouse use or tomatoes from the non-contact period for oxamyl and required this on the label it may constitute putting an off-label use on the product label. Therefore the Committee has decided to include an exemption for greenhouses in the use control but not to include the wording in the labelling control. However, if in future the exempted uses were approved by ACVM, Committee considers that it would then be acceptable to include the exemptions on the label.

The Committees revised control

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, except tomatoes grown in greenhouses, that is likely to be visited by bees if the plant or tree is in open flower or part bloom; or

(c) to any plant or tree, except tomatoes grown in greenhouses, that is likely to be visited by bees if the plant or tree is likely to flower after application within 10 days of the substance being applied.

Label statement R-9 control

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 within 10 days after application of the substance.

Review of the risks cost and benefits of the proposed control

10.92. The Committee considers that applying non-contact periods to substances containing oxamyl is likely to benefit bee health, which will have subsequent economic benefits for pollination services, the horticulture industry and honey production. However, non-contact periods would also pose non-negligible economic risks to the greenhouse tomato industry by hindering the effective control of key pest species. Therefore the Committee has applied the non-contact periods with an exemption for greenhouse use.

10.93. The Committee acknowledges that by applying an exemption full risk reduction will not be realised, however given that greenhouses provide a barrier to wild and honey bees the Committee considers that the risks to bees will be minor. The Committee also considers that the economic benefits of retaining an important pest management tool for the greenhouse industry outweighs the residual risk of exempting greenhouse tomatoes from the non-contact period. The Committee appreciates that not including the exemption in the label statements may mean that some growers are unaware of the exemption and are unable to fully benefit from it; although it considers this an incentive for manufacturers and growers to register these uses.

Review cost effectiveness of the revised control

10.94. The Committee considers that the application of controls with the identified exemptions is the most cost effective way to manage the environmental risks in balance with the economic risks to the greenhouse tomato industry of applying the proposed controls.

Committee Decision

10.95. The Committee has considered the risks, costs, benefits and cost-effectiveness of the proposed controls and considers that the variation to the E3 control is more effective for managing the risks, use and management of the substance than the current control. It considers that applying a crop-specific exemption will provide a practical balance between the needs of the greenhouse tomato industry and the broader needs to protect bees in the environment.

10.96. It also considers that requiring a label statement is more likely to achieve the purpose of the control, i.e. to protect bees, than not requiring such information on the label. However the Committee notes that the exemptions cannot currently be put on the label because the exempted uses are not approved by the ACVM Group of MPI.

10.97. Consequently the Committees revised controls (E3 and labelling) are applied to the approval for oxamyl (HSR000791).

Other relevant matters to be taken into account

Phasing-in of labelling requirements

10.98. The Committee notes that it takes time to change the labels on pesticide products because the new labels first need to be approved by ACVM and then produced and applied to products. They therefore consider it appropriate to allow a phase-in period for controls that require product labels to be changed in order to take effect.

10.99. The staff have reviewed the current labels of products covered by the approvals affected by this reassessment and found that most of the labels already include non-contact periods that meet or exceed the controls imposed under this decision. The staff have also consulted the companies whose products do not currently meet the new controls to determine how long they would need to change their labels.

10.100. Based on this consultation the Committee has decided that all of the controls described in this decision will come into effect on 1 July 2016.

The effects of the Committee's recommendation on the relationship of Māori to the environment

10.101. In their submissions and hearing presentation, Ngāi Tahu expressed concern about the limited amount and quality of data available to determine the non-contact periods and urged the Committee to apply the longest non-contact periods permitted. Ngati Huarere (Lori Anderson) raised concerns about the ability for Māori to fulfil their role as kaitiaki because the substances affected by the reassessment are toxic to bees and the environment. The particular concerns raised mentioned native bee species.

10.102. The Committee acknowledges that the information provided is not as robust as is generally desirable but, as noted above, this is often the case with older chemistry. The studies the EPA reviewed and the Committee considered were all done on honey bees so the impacts on other bee species are, as Ngāi Tahu submit, largely unknown. However, based on the information that the Committee did have it is clear that due to the nature of the crops that the substances are used on, the risks to bees, and honey bees in particular, were low whereas the risk of the substances not being available posed significant economic risks for those growers that use the affected products.

10.103. Based on the information provided, the Committee considers that the effect of the proposed changes, compared to retaining the status quo, on the relationship of Māori to the environment will be negligible. This is because the proposed change will be more protective of native bees and honey production, in which Maori have interests, than the current controls which do not contain non-contact periods. With this assessment in mind, the Committee considers that the application is consistent with the principles of the Treaty of Waitangi.

New Zealand's international obligations

10.104. The Committee did not identify any international obligations that may be impacted by the changes to the controls described in section 10.

11. Recommendations

11.1. Some submitters asked the Committee to ban the substances under consideration. This was not within the scope of the application which was limited to considering the control of non-contact periods. The Committee recommends that submitters address this matter more generally with the EPA.

11.2. Submitters also requested that the EPA ban neonicotinoid pesticides. This was not within scope of the application that the Committee was considering. The Committee recommends that submitters address this matter more generally with the EPA.

11.3. Some submitters asked that New Zealand establish national pollinator surveys and change government agricultural policies. The Committee recommends that these submitters direct their

request to the appropriate Ministries, namely the Ministry for Primary Industries and/or the Ministry for the Environment.

12.Conclusion

12.1. The Committee notes that both the presence and absence of the control has risks, costs and benefits to different parts of the agricultural industry, the environment and local communities including Māori.

12.2. The Committee notes that that although the application only asked them to set non-contact periods, they considered it appropriate to vary the controls in another way as well, i.e. to include the exemptions as they are entitled to do under section 63A(2) (a) of the Act.

12.3. The Committee considers that the revised controls strike a workable balance between the needs and interests of the different sectors and that it will result in improved protection of all bee species without causing undue economic challenges to particular industries.

Evaluation of the cost-effectiveness of the proposed controls

12.4. Subsequently the proposed controls (summarised in Table 3) are considered the most cost-effective way to manage both the economic and environmental risks posed by the substances.

Table 3 Summary of the controls

Active ingredient	Approvals affected	Non-contact period (days)	Exemptions
Acephate	HSR000154 HSR000155 HSR000156 HSR000157 HSR000158	7	Lemons
Dimethoate	HSR000188 HSR000191 HSR000193 HSR000965 HSR000129	7	None
Methamidophos	HSR000203 HSR000226	0 (no application when bees are foraging)	None
Methomyl	HSR000584 HSR007761	8	Strawberries Tomatoes grown in greenhouses
Oxamyl	HSR000791	10	Tomatoes grown in greenhouses

Overall assessment of the risks, costs and benefits

12.5. Taking into account the assessment of the potential risks and benefits associated with modifying control E3 (Regulation 49) on plant protection products containing acephate, dimethoate, methamidophos, methomyl or oxamyl, the Committee considered that, with all of the controls in place (including default, additional and variations), that:

- significant adverse impacts on the social or economic environment from the modified control and subsequent modified use pattern of the substances concerned are not anticipated (particularly in relation to the modifications made to the control on certain crops)
- significant impacts on Māori culture or traditional relationships with ancestral lands, water, sites, wāhi tapu, valued flora and fauna or other taonga that will breach the principles of the Te Tiriti o Waitangi/Treaty of Waitangi are not anticipated; and
- benefits will be derived for New Zealand by allowing the use of the specified OPC substances in the proposed manner
- the proposed variation is not expected to affect New Zealand's international obligations.

13.Decision

13.1. Pursuant to section 63A of the Act, the Committee has considered this application to apply non-contact periods to plant protection products containing acephate, dimethoate, methamidophos methomyl or oxamyl (approvals specified in Table 3). In doing so, the Committee has applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 ("the Methodology") as detailed in the decision path and explanatory notes (see Appendix B).

13.2. The Committee considers that, with the revised controls in place, the overall risks associated with these substances are non-negligible, but that the benefits associated with their use are also non-negligible and are sufficient to outweigh the risks.

13.3. Therefore, the Committee approves the variation to the approvals in accordance with clause 27 of the Methodology and the amended controls as listed in Appendix A.

Helen Atkins	**Date: 7 August 2015**
Chair, Decision Making Committee Environmental Protection Authority	

Appendix A: Full ccontrols applying to all reassessed substances.

The modifications made by this decision have been integrated into the full set of controls for Organophosphate and Carbamate Pesticides, which were published under application APP201045 as *Decision Annex – Controls* and include the subsequent minor and technical amendments to those controls. Please see this document for the controls.

Appendix B: Decision Path

Flowchart: Decision path for modified reassessment for amendments to hazardous substance approvals: application made and determined under section 63A.

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

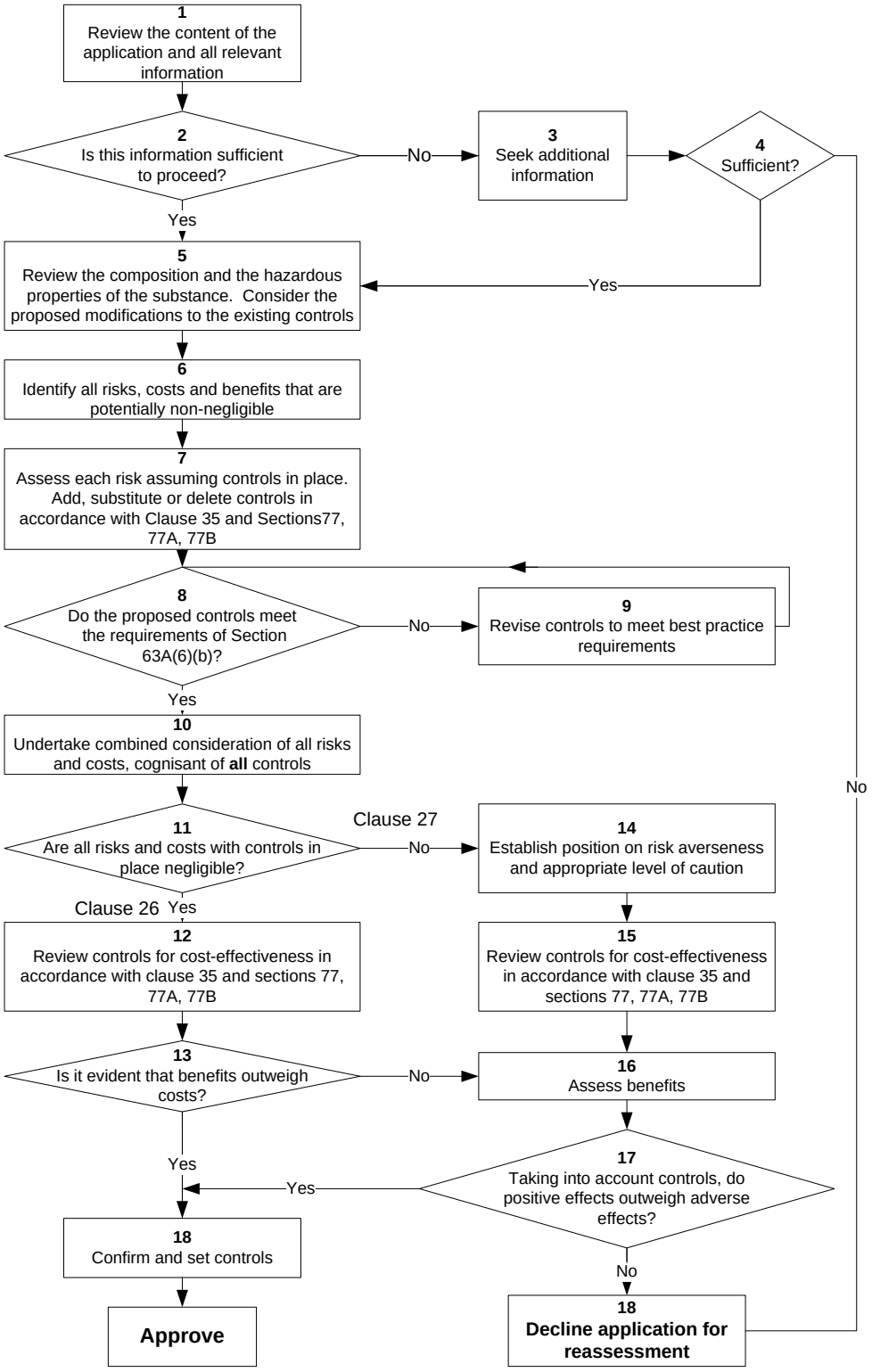


Figure 1A Explanatory Notes

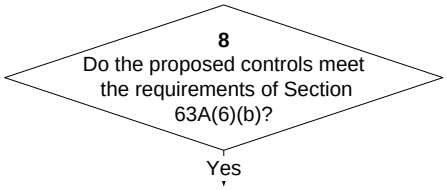
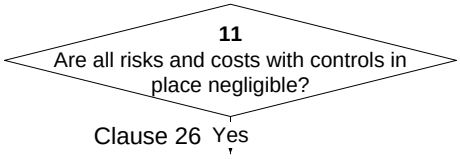
Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report, and information received from experts and that provided in submissions (where relevant) in terms of section 28(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology. While section 63A is not mentioned in section 53 (public notification), sections 63A(4) and (5) provide discretion for the HSNO decision maker to consider public notification (cf section 53(2)) and guidance re consultation where an application is not publicly notified.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision.
Item 3:	**(if 'no') Seek additional information** If there is not sufficient information then additional information may need to be sought under section 52 or 58 of the Act. If the applicant is not able to provide sufficient information for consideration then the application is not approved. In these circumstances the HSNO decision maker may choose to decline the application, or the application may lapse.
Item 4	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application for reassessment must be declined (see item 18).
Item 5:	**(if 'yes' from item 2 or from item 4) Review the composition and the hazardous properties of the substance, and the proposed modifications to the existing controls** Review the composition of the substance, its hazardous properties, and the existing suite of controls on the substance. The level of detail for this review will depend on the nature of the application for modified reassessment. In most cases a detailed review will not be required. Consider the proposed modifications to the existing controls.
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible**[6] The modified reassessment process concentrates on a specific aspect of the approval (section 63A(1)(a)). All risks, costs and benefits that are potentially non-negligible need to be identified. However, emphasis should be placed on effects that are expected to change as a result of the proposed changes to controls. Costs and benefits are defined in the Methodology as the value of particular effects. However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally synonymous and may be addressed together.

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

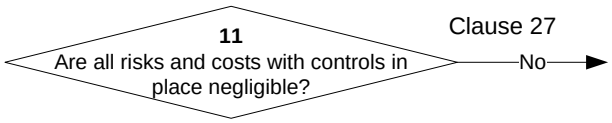
	Examples of costs that cannot be considered as risks are one-off direct financial costs incurred by applicants that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise they will considered in the same way as risks, but their likelihood of occurrence will be more certain. Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).	
	Step 1:	Identify all possible risks and costs (adverse effects) and benefits (positive effects) associated with the approval of the substance(s), and based on the range of areas of impact described in clause 9 of the Methodology and sections 5 and 6 of the Act[7]. Consider the effects of the substance through its lifecycle (clause 11) and include the likely effects of the substance being unavailable (sections 29(1)(a)(iii) and 29(1)(b)(iii)). Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14). Consider short term and long term effects. Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.
	Step 2:	Document those risks, costs and benefits that can be readily concluded to be negligible[8], and eliminate them from further consideration. Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.
Item 7:	**Assess each risk assuming controls in place. Add, substitute or delete controls in accordance with clause 35 and sections 77, 77A and 77B of the Act.** The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. The assessment is carried out with the default controls in place. Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of its occurring. Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account. The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost. This assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and	

[7] Effects on the natural environment, effects on human health and safety, effects on Maori culture and traditions, effects on society and community, effects on the market economy.

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

	how significant the uncertainty is for the decision (clause 29(a)). Consider the HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls. See EPA report 'Approach to Risk' for further guidance[9]. Where it is clear that residual risks are non-negligible and where appropriate controls are available, add substitute or delete controls in accordance with sections 77 and 77A of the Act to reduce the residual risk to a tolerable level. If the substance has toxic or ecotoxic properties, consider setting exposure limits under section 77B. While clause 35 is relevant here, in terms of considering the costs and benefits of changing the controls, it has more prominence in items 12 and 15. If changes are made to the controls at this stage then the approach to uncertainty and the approach to risk must be revisited.
Item 8:	**Do the proposed controls meet the requirements of Section 63A(6)(b)?** Consider whether the proposed controls meet best international practices and standards for the safe management of hazardous substances. This includes the full suite of proposed controls including existing controls and modified controls.
Item 9:	**(if 'no' from item 8) Revise controls to meet best practice requirements** If the controls do not meet the best international practice criteria, then modify the controls so that they do meet them.
Item 10:	 **(if 'yes' from item 8) Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually consider all risks and costs together as a 'basket' of risks/costs. If it is feasible and/or appropriate, this may involve combining groups of risks and costs as for Clause 34 of the Methodology. The purpose of this step is to consider synergistic effects and determine whether these may change the level of individual risks.
Item 11:	**Are all risks and costs with controls in place negligible?** Looking at individual risks in the context of the 'basket' of risks, consider whether any of the residual risks (costs) are negligible.
Item 12:	

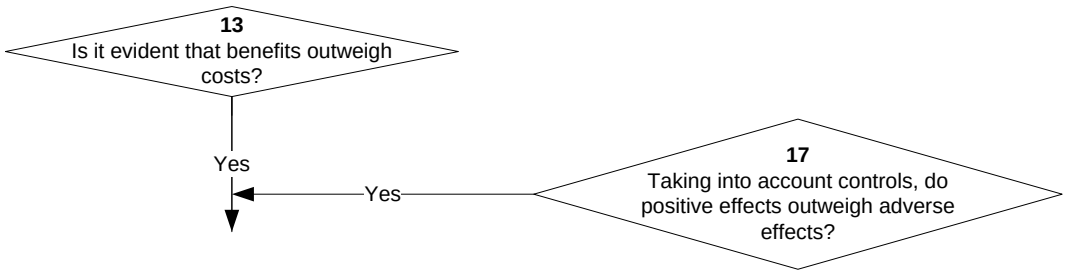
9 http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

	(if 'yes' from item 11) Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B Where all risks are negligible the decision must be made under clause 26 of the Methodology. Consider the cost-effectiveness of the proposed individual controls and exposure limits. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and the cost-effectiveness of the full package of controls.
Item 13:	**Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 9). In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 7. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs[10]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs. However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 16).
Item 14:	 **(if 'no' from item 10) Establish HSNO decision maker's position on risk averseness and appropriate level of caution** Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).
Item 15:	**Review controls for cost-effectiveness in accordance with clause 35 and sections 77, 77A and 77B** This constitutes a decision made under clause 27 of the Methodology (taken in sequence from items 10, 13, 14 and 15). Consider (a) whether any of the non-negligible risks can be reduced by varying the controls in

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

	accordance with section 77 and 77A of the Act, and (b) the cost-effectiveness of the controls. Where relevant and appropriate, add, substitute or delete controls whilst taking into account the view of the applicant, and making sure that the benefits of doing so outweigh the costs. As for item 6, If the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.
Item 16:	**(if 'no' from item 13, or in sequence from item 15) Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of its occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect. An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[11]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs. As for risks and costs the assessment is carried out with the default controls in place.
Item 17:	**Taking into account controls, do positive effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 5, 7 (9), 12 and/or 15. Where this item is taken in sequence from items 14, 15 and 16 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 11, 12 and 13 (i.e. risks are negligible, and there are external or public costs) it constitutes a decision made under clause 26 of the Methodology.
Item 18:	**(if 'no' from item 4 or item 17) Decline application for reassessment** (from item 4) The Act is silent on the situation if there is insufficient information to consider the application. However, sections 55-61 (section 63A(3)) are deemed to hold, therefore the HSNO decision maker concludes that the application for reassessment may be declined if there is insufficient information. (from item 17) The HSNO decision maker may decline the application under section 63A(6) after taking into account the effects of the substance and best international practices and standards. Section 63A(2)(b) notes that this modified reassessment process cannot result in an approval to import or manufacture the substance being revoked. Therefore, if the process results in a 'decline' decision, then the result is that the modified reassessment of the substance is not approved, and

[11] Clause 13 of the Methodology

	the existing controls remain in force.
Item 19:	 **(if 'yes' from items 13 or 17) Confirm and set controls** Controls have been considered at the earlier stages of the process (items 5, 7 (9), 12 and/or 15). The final step in the decision-making process brings together all the proposed controls, and reviews them for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

Appendix C: Standard terms and abbreviations

ai	active ingredient
ALD50	approximate median lethal dose, 50%
AOEL	acceptable operator exposure level
ARfD	acute reference dose
as	active substance
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
BSAF	biota-sediment accumulation factor
bw	body weight
c	centi- ($x10^{-2}$)
CA	controlled atmosphere
CI	confidence interval
CL	confidence limits
CNS	central nervous system
COD	chemical oxygen demand
DFR	dislodgeable foliar residue
DO	dissolved oxygen
DOC	dissolved organic carbon
DT50	period required for 50 percent dissipation (define method of estimation)
DT90	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
ED50	median effective dose
ERC	environmentally relevant concentration
F	field
F0	parental generation
F1	filial generation, first
F2	filial generation, second
fp	freezing point
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionization detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
I	indoor

I50	inhibitory dose, 50%
IC50	median immobilization concentration or median inhibitory concentration 6
ID	ionization detector
Im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
iv	intravenous
IVF	in vitro fertilization
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H)
Kads	adsorption constant
Kdes	apparent desorption coefficient
Koc	organic carbon adsorption coefficient
Kom	organic matter adsorption coefficient
kg	kilogram
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC50	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD50	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSS	liquid scintillation spectrometry
LT	lethal threshold
M	molar
µm	micrometer (micron)
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
MLT	median lethal time
MLD	median lethal dose
mol	Mole(s)
MOS	margin of safety
mp	melting point
MS	mass spectrometry
MSDS	material safety data sheet
NAEL	no adverse effect level
nd	not detected
NEL	no effect level
ng	nanogram
nm	nanometer
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NR	not reported
OC	organic carbon content
ODP	ozone-depleting potential

OM	organic matter content
Pa	pascal
PEC	predicted environmental concentration
PECS	predicted environmental concentration in soil
PECSW	predicted environmental concentration in surface water
PECGW	predicted environmental concentration in ground water
PHI	pre-harvest interval
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
POW	partition coefficient between n-octanol and water
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PTDI	provisional tolerable daily intake
r	correlation coefficient
r2	coefficient of determination
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RL50	median residual lifetime
RP	reversed phase
RRT	relative retention time
RSD	relative standard deviation
sc	subcutaneous
SD	standard deviation
se	standard error
SF	safety factor
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
spp	subspecies
SSD	sulphur specific detector
STEL	short term exposure limit
t½	half-life (define method of estimation)
TCLo	toxic concentration, low
TER	toxicity exposure ratio
TIFF	tag image file format
TOC	total organic carbon
TWA	time weighted average
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
w/v	weight per volume
ww	wet weight
w/w	weight per weight