
DECISION

8 May 2020

Summary

Substance	Diazinon, Fenamiphos and Methamidophos
Application code	APP203975
Application type	To decide whether there are grounds for reassessment under the Hazardous Substances and New Organisms (HSNO) Act 1996 ("the Act")
Applicant	Vegetable Research and Innovation (VR &I) Board
Purpose of the application	To determine whether grounds for reassessment exist for diazinon, fenamiphos and methamidophos plant protection substances, with a view to applying for a reassessment to extend the phase-out timings
Date application received	12 February 2020
Consideration Date	26 March 2020 to 8 May 2020
Considered by	A Decision-Making Committee of the Environmental Protection Authority ("EPA")
Decision	Grounds exist for the reassessment of substances containing diazinon, fenamiphos or methamidophos, used for plant protection purposes

1. Background

- 1.1. The applicant has applied to determine whether grounds exist to reassess approved substances containing diazinon, fenamiphos or methamidophos used for plant protection purposes. The purpose of a subsequent reassessment would be to extend the phase-out periods assigned to the approvals as a consequence of the reassessment APP201045.
- 1.2. The hazardous substances detailed in Table 1 contain diazinon, fenamiphos or methamidophos and are used for plant protection purposes. This list is provided for information purposes only. A reassessment application based on this grounds for reassessment decision may include all or some of the substances listed in Table 1, as well as any substances containing diazinon, fenamiphos or methamidophos approved in the interim period between this decision and receipt of the reassessment application. The list of affected approvals provided by the applicant has been supplemented by other approvals considered to fall within the scope of the application.

Table 1. Approvals for plant protection substances containing diazinon, fenamiphos or methamidophos. Approvals identified in italics were not identified by the applicant, but are considered to be relevant to the scope of the proposed reassessment.

Active ingredient	HSNO Approval Number	Trade name
Diazinon	HSR101016	Dianex Diazate
	HSR000180	Dew 600 Diazol Insecticide Zagro Diazinon 600EW
	HSR000181	Digrub
	HSR000175	Gesapon 20G Diazinon 20G
	HSR002481	Diazol 800
	<i>HSR000174</i>	<i>No trade name products identified</i>
	<i>HSR000176</i>	
	<i>HSR000177</i>	
	<i>HSR000178</i>	
	<i>HSR000179</i>	
	<i>HSR000182</i>	
	<i>HSR000183</i>	
<i>HSR000184</i>		
<i>HSR007700</i>		
<i>HSR100760</i>		
<i>HSR100878</i>		

Active ingredient	HSNO Approval Number	Trade name
Fenamiphos	HSR000956	Nemacur Fenafos 400
	HSR007769	Nematak 400EC
	HSR100282	Canyon
	<i>HSR000198</i> <i>HSR002480</i> <i>HSR007894</i>	<i>No registered trade name products identified</i>
Methamidophos	HSR000226	Metafort 60SL Methafos 600
	<i>HSR002863</i>	<i>Methamidophos active ingredient</i>
	<i>HSR000203</i>	<i>No registered trade name products identified</i>

- 1.3. The substances are subject to controls appropriate to the assigned hazard classifications, as well as a number of additional and varied controls, set to the substances in reassessment application APP201045. In addition, the identified substances are to be phased out in accordance with the specified approval expiry dates.
- 1.4. The purpose of this application is to decide whether there are grounds for the reassessment of the substances.

2. Application process

- 2.1. The application was formally received by the EPA on 12 February 2020 and the information supplied was evaluated by EPA staff.
- 2.2. Consideration of the application took place between 26 March 2020 and 8 May 2020 by a decision-making committee of the EPA.

3. Evaluation against the criteria in the Act

- 3.1. The Act specifies a number of factors that the EPA has to take into account when considering whether grounds exist for a reassessment. At least one of these factors must be present before the EPA can use its discretion to determine whether there are grounds for a reassessment.
- 3.2. The Committee notes that detailed analysis of the information provided has not been undertaken when determining whether grounds exist. Greater scrutiny of the information is carried out in the evaluation of a subsequent reassessment application, should grounds to reassess be established.

Significant new information relating to the effects of the substance has become available (section 62(2)(a))

- 3.3. The applicant has provided information about the effects of the substances in the context of the positive effects that they present.
- 3.4. The information is contained in the following documents:

- Appendix 1 to the application;
 - Confidential Appendices 2 and 3 to the application.
- 3.5. The information described the efforts that were made to identify viable alternatives to the substances since the 2013 reassessment decision, from the perspective of the applicant. It was the applicant's position that viable alternative substances for numerous critical uses were not yet identified.
- 3.6. On the presumption that the information provided by the applicant is a correct and complete representation of the current state of affairs, the Committee considered that the information provided was "significant":
- 3.6.1. The DMC for APP201045 considered that, with ten years of research and testing, that viable alternatives would have been identified and made available, reducing the level of reliance on, and therefore benefit offered by, the substances. As a consequence it was considered at that time that the adverse effects would outweigh the beneficial effects at the end of the specified phase-out period.
- 3.6.2. However, if the apparent lack of viable alternatives being identified is correct, the risk and benefits balancing remains finely balanced as it was at the time of the 2013 decision (ie the beneficial effects narrowly outweigh the adverse effects), rather than achieving the projected expectation of the DMC. Consequently, the Committee consider that is significant in the context of the continued appropriateness of the phase-out periods.
- 3.7. The Committee also noted that the information supplied is considered as 'new' as it was not available during the reassessment application, APP201045.

A change in controls under the Health and Safety at Work Act 2015 (section 62(2)(aa))

- 3.8. This factor is not relevant to this application.

Another substance with similar or improved beneficial effects and reduced adverse effects has become available (section 62(2)(b))

- 3.9. This factor is not relevant to this application.

Information showing a significant change of use has become available (section 62(2)(c))

- 3.10. The applicant provided information about changes in use of the substances.
- 3.11. The information is contained in Appendix 1 to the application.
- 3.12. The applicant provided information that identified how the use of the substances had changed since the 2013 reassessment. This included restrictions imposed through other regulatory action in New Zealand (ie the Ministry of Primary Industries' 2015 reassessment). The applicant identified that a key outcome of that action was to prohibit off-label use, which effectively removed uses in a number of cropping situations. The applicant also identified use of the OPCs for biosecurity incursion responses, using brown marmorated stink bug as an example.
- 3.13. The Committee considered that the information provided did not show that the change of use was "significant" on the basis that the uses of the OPCs have not changed substantively from what was reviewed and assessed in the previous reassessment: the OPCs are still used for plant protection purposes in horticulture production, though the range of specific horticultural uses appears to have reduced. The overall effect of changes in usage in specific crop production is more relevant to the

discussion on new information relating to the effects of the substances and the balance of risks and benefits, discussed previously.

- 3.14. In regards to the specific case of use of the OPCs as a biosecurity tool against incursions of brown marmorated stink bug, the Committee considered that while OPCs may offer potential value for this purpose they are not currently considered frontline options by MPI and therefore this use does not represent a current change in use or practice. Therefore this is not information that contributes to the determination of this grounds factor.

Information showing a significant change in the quantity manufactured, imported, or developed has become available (section 62(2)(c))

- 3.15. The applicant provided information about changes in the quantities of the substances manufactured or imported.
- 3.16. The information is contained in Confidential Appendix 1 to the application.
- 3.17. The applicant provided information that indicates that there has been a change in the volumes imported or manufactured since the previous reassessment.
- 3.18. The Committee considered that, while the information provided appears to represent a change in volumes, this does not represent a significant change in the context of the previous reassessment decision, as there was an anticipation and an intention by the DMC that, over time, there would be a reduction in the use of the OPCs.

Other reasons for requesting a reassessment under section 62(2)

- 3.19. The applicant provided information about biosecurity threats that were not key concerns at the time of the previous reassessment. The applicant argues that, if the phase-out periods are allowed to run their course, then timely access to potential biosecurity management options may not be available.
- 3.20. The applicant considered that ensuring on-going availability of these substances to ensure timely access to biosecurity tools is consistent with principles and matters relevant to the purpose of the Act (Sections 5 and 6).
- 3.21. The Committee noted the information provided by the applicant in coming to a decision. It notes that the use of OPCs as tools for biosecurity was a key consideration in the original reassessment. At that time, the DMC was concerned with reaching a decision that ensures “the suite of tools available for plant protection and biosecurity was not seriously undermined.” Should grounds be established, then the specific example of brown marmorated stink bug could be considered in the context of a subsequent reassessment. It is also noted the commentary provided in submissions on the 2013 reassessment.

4. Issues and concerns to Māori

- 4.1. The Committee has considered Māori perspectives regarding the applicant’s application to determine whether there are grounds for the reassessment of the substance. The Committee noted that, if this application is approved and a subsequent reassessment applied for, wider public notification and/or consultation will be undertaken, including with Iwi/Māori.
- 4.2. The Committee considered that there were no issues related to the principles of the Treaty of Waitangi to be addressed in the context of this application. The Committee noted that these principles will be considered if a subsequent reassessment application is received.

5. International obligations

- 5.1. The Committee has considered New Zealand's international obligations regarding the applicant's application to determine whether there are grounds for the reassessment of the substance.
- 5.2. The Committee noted that these international obligations will be considered if a subsequent reassessment application is received.

6. Consideration

- 6.1. The Committee considered that there is significant new information relating to the effects of the substance. Specifically, this new information is interpreted solely as a lack of viable alternatives to diazinon, fenamiphos and methamidophos where such alternatives were anticipated in the outcome of APP201045 to be available at the time of phase out indicated in the previous reassessment.
- 6.2. Taking that into account, the Committee considered that grounds exist under section 62 of the Act for the reassessment of plant protection products containing diazinon, fenamiphos or methamidophos, on the basis that significant new information about the effects of the substance has become available (section 62(2)(a)).
- 6.3. The Committee noted that, although it considered that grounds exist to reassess these substances, no inference can be drawn from this decision, or assumptions made, as in regards to the outcomes of any subsequent reassessment of these substances.



Signed by:

Date: 8 May 2020

Dr John Taylor
Chair, Decision Making Committee
Environmental Protection Authority
