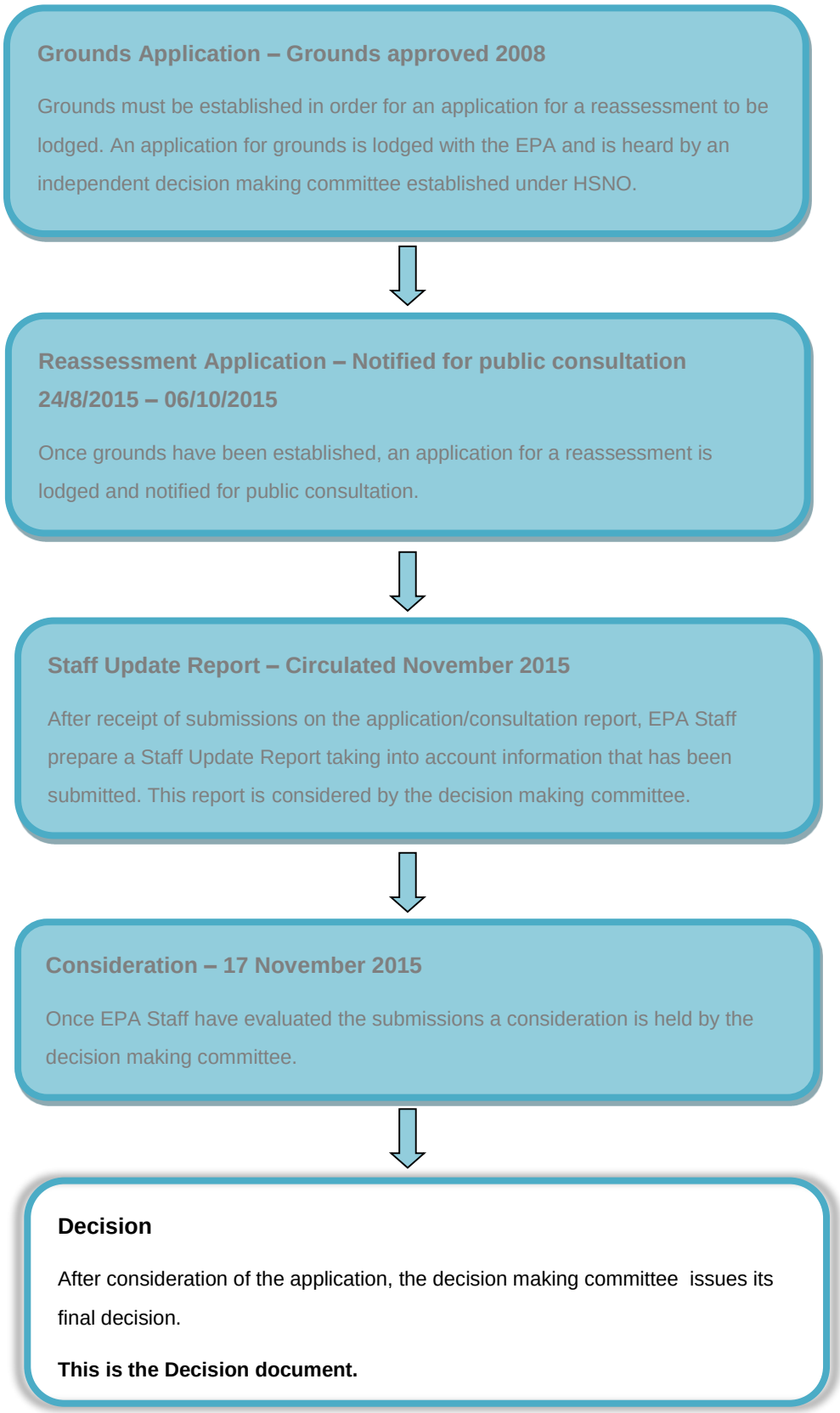
Application for the Reassessment of a Group of Hazardous Substances

under Section 63 of the Hazardous Substances and New Organisms Act 1996

26 January 2016

APP202098: Reassessment of carbaryl, chlorpyrifos and diazinon used in veterinary medicine and other non-plant protection purposes

Overview of the reassessment process



1. Summary of decision

Veterinary medicine substances for reassessment	HSNO Approval number	Decision
Liquid containing 1.4 - 2.6% 2-hydroxybenzoic acid, 0.7 - 1.3% **carbaryl** and 0.11 - 0.29% chlorocresol (trade name Fido's Ear Drops)	HSR001825	Approved
Flammable liquid containing 7 – 13 g/L **chlorpyrifos** and 100 – 120 g/L cypermethrin (trade name FLYPEL)	HSR001812	Declined
Flammable liquid containing 120 - 180 g/L **chlorpyrifos** (trade name Xterminate 10)	HSR001814	Declined
Flammable liquid containing 32 – 50% **chlorpyrifos** (no trade name products identified)	HSR001816	Declined
Collar containing 140 - 180 g/kg **diazinon** and 1.7 - 3.2 g/kg pyriproxyfen (trade names PetScience Flea Collar Plus for Cats & Kittens, PetScience Flea Collar Plus for Dogs & Puppies)	HSR001802	Declined
Collar containing 140 - 180 g/kg **diazinon** (trade names VitaPet 5 Month Flea Collar For Dogs, VitaPet 5 Month Flea Collar For Cats, Pet Team Flea Collar for Dogs, Pet Team Flea Collar for Cats)	HSR001807	Declined
Flammable liquid containing 360 - 440 g/litre **diazinon** (trade name TopClip 40)	HSR001953	Declined
Solid containing 20 – 50 g/kg **diazinon** (no registered trade name products identified)	HSR001808	Declined
Flammable liquid containing 0.26 – 5% **diazinon** (no registered trade name products identified)	HSR002288	Declined

Non-plant protection substances for reassessment	HSNO Approval number	Decision
Dustable powder containing 50 g/kg **carbaryl** (trade name Kiwicare No Wasps Insecticidal Dust)	HSR000672	Declined
Wettable powder containing 800 g/kg **carbaryl** (trade name Kiwicare Carbaryl Insect Control; Wasp	HSR000819	Declined
Ready to use bait containing 5 g/kg **chlorpyrifos** (no registered trade name products identified)	HSR000164	Declined

Paste containing 5 g/kg **chlorpyrifos** (no registered trade name products identified)	HSR000166	Declined
Microencapsulated suspension concentrate containing 200 g/L **chlorpyrifos**	HSR000168	Declined
Emulsifiable concentrate containing 240 g/litre **chlorpyrifos**	HSR000169	Declined
Ready to use liquid containing 20 g/litre **chlorpyrifos** (no registered trade name products identified)	HSR000172	Declined
Flammable liquid containing 2.5 – 3% **chlorpyrifos** (no registered trade name products identified)	HSR001810	Declined
General purpose insect spray (contains **diazinon**) (no registered trade name products identified)	HSR001741	Declined
Aerosol containing 0.3 – 0.7% **carbaryl** and 0.4 – 0.8% piperonyl butoxide	HSR001811	Declined

2. Background

2.1. Scope

2.1.1. The Environmental Protection Authority (EPA) is reassessing substances containing carbaryl, chlorpyrifos and diazinon (CCD) used in veterinary medicines and other non-plant protection products because of concerns about the safety and well-being of people and the environment arising from their use.

2.1.2. Chlorpyrifos and diazinon are organophosphates, and carbaryl is a carbamate compound. These organophosphates and carbamates (OPCs) are insecticides used against a broad range of insect pests for a variety of purposes including veterinary medicines and potentially for non-plant protection uses such as public health (e.g. for pest control in hospitals, restaurants etc.), and industrial uses (e.g. for building, warehouse or industrial structure pest control).

2.1.3. The acute health effects resulting from exposure to high levels of OPCs are well known from animal studies and numerous human poisoning incidents. Short term exposure can result in symptoms including increased sweating and salivation, dizziness, fatigue, runny nose or eyes, nausea, intestinal discomfort, confusion and changes in heart rate. At high levels of exposure more severe effects such as paralysis, seizures, loss of consciousness and death may occur.

2.1.4. As well as acute toxicity, there are concerns over the potential for OPCs to cause longer term adverse health effects in humans. These include the potential for chronic health effects following acute poisoning, and effects as a result of chronic exposure to lower levels that do not cause the clinical signs or symptoms of poisoning.

2.1.5. OPCs are also harmful to the environment. They are very toxic to the aquatic environment and to terrestrial invertebrates (e.g. bees).

2.2. Purpose of this document

2.2.1. This document has been prepared by the Decision Making Committee (the Committee) for this application. It outlines our assessment of the available information, and notifies our decision on the use of substances containing CCD covered in this application.

3. The reassessment of CCD

3.1. Grounds

3.1.1. In 2009, the Environmental Risk Management Authority of New Zealand (ERMA New Zealand, now the EPA) established grounds to reassess the approvals for substances containing diazinon, and grounds to reassess carbaryl and chlorpyrifos were established in 2012, in accordance with section 62 of the Hazardous Substances and New Organisms (HSNO) Act (the Act). In reaching that decision, ERMA New Zealand noted the following:

- Overseas regulatory action had led to the withdrawal/phasing out of CCD in Europe (and certain products in North America), the adoption of more stringent measures for domestic and agricultural use in the USA and Canada, and the possible adoption of more stringent measures in Australia.
- The reassessment of CCD was aligned with the principles of ERMA New Zealand's Risk Reduction strategy.

3.2. Substances and approvals for reassessment

3.2.1. There are 19 HSNO approvals in total covered by this reassessment, pertaining to substances containing carbaryl, chlorpyrifos or diazinon; nine for use in veterinary medicines and ten for non-plant protection uses.

3.3. The application

3.3.1. An application for the reassessment was prepared by EPA staff on behalf of the Chief Executive under section 63 of the Act.

3.3.2. EPA staff sought information from a wide range of sources on the way that the substances are used in New Zealand. The risk assessments were conducted on use patterns as recommended on the product labels and through consultation with industry representatives, and included information obtained via the call for information on the application in 2014.

3.3.3. During these rounds of stakeholder engagement and data gathering, feedback was also sought on the practicality, economic viability and sustainability of proposed additional controls, and on the benefits associated with use of the substances for specific sectors.

3.3.4. The Chief Executive submitted the application for reassessment on 25 August 2015.

3.4. Legislative basis for the application

3.4.1. The application for the reassessment was lodged pursuant to section 63 of the Act and, as required under that section, deemed to be an application made under section 29 of the Act. Section 29 requires the Committee to consider positive and adverse effects of the substance and to make a decision based on whether or not the positive effects of the substance outweigh the adverse effects of the substance.

3.4.2. Consideration of the application followed the relevant sections of the Act and the decision-making Methodology established under section 9 of the Act.

3.5. Appointment of the Committee

3.5.1. The following members of the HSNO Committee were appointed in accordance with the Crown Entities Act 2004 to consider the application in accordance with a delegation under section 19(2)(b): Dr Deborah Read (Chair), Dr Kevin Thompson, and Dr Louise Malone.

3.6. Timeline

3.6.1. The timeline for the application was as follows:

Action	Date
Application formally received	11 August 2015
Application publicly notified	25 August 2015
Public submissions closed	6 October 2015
Staff Update Report circulated	3 November 2015
Consideration held	17 November 2015

3.7. Notification of the application

3.7.1. In accordance with section 53 of the Act, the application was publicly notified on the EPA website on 25 August 2015. Notification was sent to recipients of the relevant interested parties' email lists, and media alerts were issued.

3.7.2. The Minister for the Environment was advised of the application on 25 August 2015 in accordance with section 53(4)(a) of the Act.

3.7.3. An application summary was also sent to government agencies which were identified as having a specific interest in the application and interested parties who had previously indicated that they wished to be notified of this application in accordance with section 53(4)(b) of the Act.

3.8. Staff Update Report

3.8.1. EPA staff prepared a Staff Update Report to provide the Committee and submitters with a review of the submissions received in response to the public notification of the reassessment application.

3.8.2. In preparing this report, EPA staff reviewed all the submissions and prepared responses to significant issues raised. The Staff Update Report was circulated on 3 November 2015.

3.9. Information available for the consideration

3.9.1. The Committee had available for its consideration the following:

- Reassessment application
- Staff Update Report

- NZIER cost benefit analysis
- The Use of Diazinon as a Veterinary Medicine in New Zealand: A Report to ERMA New Zealand (AgResearch)
- Five written submissions

3.10. Public consultation and the consideration

3.10.1. Five submissions were received during the public notification period; two supported the proposals outlined in the application, two neither supported nor opposed the proposals, and one opposed the proposals.

Table 1 Submissions received

Submission Number	Submitter	Submitter Organisation (if relevant)
111533		WorkSafe New Zealand - Auckland
111549	Oliver Sutherland	Te Rūnanga o Ngāi Tahu (Ngāi Tahu)
111551	John Hicking	Orion Crop Protection Ltd
111555	Ann Thompson	Federated Farmers of New Zealand (Incorporated)
111550	Chris Houston	Beef and Lamb New Zealand Ltd

3.10.2. Key points from the submissions are addressed throughout this document.

3.10.3. A consideration meeting was convened in accordance with section 60 of the Act and clause 2(b) of the HSNO Methodology. The consideration was held by teleconference on 17 November 2015.

4. Treaty of Waitangi (Te Tiriti ō Waitangi)

4.1. Introduction

4.1.1. Under section 8 of the Hazardous Substances and New Organisms Act (1996), all persons exercising powers and functions under the Act are to take into account the principles of the Treaty of Waitangi (Tiriti ō Waitangi).

4.1.2. In reference to the principles of the Treaty of Waitangi, the Committee focused its attention on the generally accepted principles of partnership, participation and protection.

4.1.3. The principles of partnership and participation refer to the shared obligation on both the Crown and Māori to act reasonably, honourably and in good faith towards each other to ensure the making of informed decisions on matters affecting the interests of Māori. Additionally, the Waitangi Tribunal has previously recommended that "Environmental matters, especially as they may affect Māori access to traditional food resources also require consultation with Māori people concerned."[1]

4.1.4. The Crown's duty of active protection is the obligation to take positive steps to ensure Māori interests are protected. Further, that this protection is not merely passive but extends to active protection of Māori people in the use of their lands and waters to the fullest extent practicable.

4.2. Response from submitters

4.2.1. The Committee considered the written submission from Dr Oliver Sutherland on behalf of the Ngāi Tahu HSNO committee.

4.2.2. The Ngāi Tahu HSNO committee expressed support for the "*phasing out of all products containing chlorpyrifos, diazinon and carbaryl with the exception of the ear drop product for cats and dogs*".

4.2.3. Ngāi Tahu supports the environmental risk assessment undertaken by the EPA, but noted that "*the risk of environmental or other risk resulting from the disposal of used/broken/fallen off flea collars is not mentioned. We do not know how significant this risk would be, but given that it may well occur in a domestic setting it should have at least been acknowledged*".

4.2.4. Ngāi Tahu also suggested that the sheep farming and shearing industries should be made aware of the results of the human health risk assessment ,especially in relation to past exposure. The Committee recommends that the EPA draw this to the attention of WorkSafe New Zealand.

4.2.5. The Committee noted that submissions from WorkSafe New Zealand, Beef + Lamb New Zealand Ltd and Federated Farmers of New Zealand (Incorporated) acknowledged the human health risks associated with CCD.

[1] P. McDonald (September 1991) "Consultation with Iwi" Planning Quarterly pp8-10

5. Hazard classifications

5.1.1. As part of the reassessment, EPA staff reviewed the HSNO classifications for CCD and formulations containing these substances. A number of changes to the classifications were proposed.

5.1.2. Classifications for the active ingredients were reviewed based on data from international regulators and other authorities. For the formulated substances containing the active ingredients, classifications took into account:

- The revised classifications for the active ingredients
- Changes in the mixture rules applied by the EPA in establishing classifications (summation, rather than additivity, is now used for mixture rules to derive ecotoxicity classifications for mixtures)
- Any changes in the classification of the other components of the mixtures that may have occurred since the original classification was carried out.

5.1.3. The Committee has adopted the classifications listed in Table 2.

Table 2 Summary of the new classifications for carbaryl containing formulation - Fido's Ear Drops

Substance Name	Approval Number	Current Classification	New Classification
Liquid containing 1.4 - 2.6% 2-hydroxybenzoic acid, 0.7 - 1.3% carbaryl and 0.11 - 0.29% chlorocresol	HSR001825	6.1E (oral), 6.1E (dermal), 6.3B, 6.4A, 6.5B, 6.7B, 6.9B (oral), 9.1C, 9.4C	**Add** 9.2D, 9.3C **Remove** 6.1E (oral), 6.1E (dermal), 6.4A **Change** 9.1C to 9.1A; 9.4C to 9.4B

6. Assessment of benefits

6.1. Summary

6.1.1. The Committee's view, set out in more detail below, is that the benefits from substances containing carbaryl, chlorpyrifos or diazinon are negligible other than for the carbaryl based product "Fido's Ear Drops".

6.2. Introduction

6.2.1. The Committee reviewed the EPA staff assessment of the potential benefits of all the substances containing carbaryl, chlorpyrifos and diazinon listed in the application. In addition, the Committee considered the submission from Orion Crop Protection, which specified potential benefits from the use of the diazinon based sheep dip - TopClip.

6.3. Benefits from veterinary use

Benefits from TopClip

6.3.1. In relation to benefits, the Committee noted all the points in the EPA Staff Update Report and from submitters, and in general agreed with the conclusions in the Staff Report.

6.3.2. Orion Crop Protection Ltd considers that if this substance is withdrawn from the market, users may shift to another low cost alternative organophosphate product. If the chlorpyrifos based products (which are not currently being manufactured) also have their approvals revoked, the only alternative organophosphate product would be one containing propetamphos, which is used in an equivalent way.

6.3.3. Orion Crop Protection Ltd stated that propetamphos is more acutely toxic than diazinon. The Committee agreed that a shift to propetamphos might be a potential adverse outcome of this decision, however, without a full review of the risks, costs and benefits of propetamphos it is not possible to conclude whether this is a better or worse alternative than diazinon. Comparing the hazard classifications of the products is not a sufficient assessment. The Committee also noted that there are other alternatives to propetamphos available for the treatment of ectoparasites of sheep.

6.3.4. EPA staff expect organophosphate products containing propetamphos will be included in a future EPA reassessment. The Committee does not want to encourage the use of an alternative, more toxic organophosphate and considered that substances containing propetamphos should be reassessed as soon as possible by the EPA.

6.3.5. Although the Committee considered that there are some benefits associated with continued use of TopClip, these do not appear to be significant given the availability of non-organophosphate alternatives. The Committee therefore considered these benefits to be negligible.

Benefits from diazinon flea collars for cats and dogs

6.3.6. The Committee considered the potential benefits from using diazinon in flea collars on cats and dogs, and found them to be negligible.

Benefits from carbaryl based ear drops – Fido's Ear Drops

6.3.7. The Committee considered the benefits outlined in the application, and concluded that the benefits from use of carbaryl containing ear drops include efficacy in treating pests, and ease with which the product can be applied. The Committee considered these benefits to be non-negligible.

6.4. Benefits from non-plant protection use

6.4.1. The Committee noted that there are no perceivable benefits to be derived from the ongoing use of CCD for non-plant protection applications, particularly as they are no longer used in New Zealand.

6.5. Human health benefits

6.5.1. The Committee considered that there are no human health benefits to be derived from the use of CCDs.

6.6. Benefits to Māori

6.6.1. No specific benefits to Maori have been identified.

6.7. Benefits to society and communities

6.7.1. EPA staff identified a positive effect on society and communities in terms of reducing anxiety associated with expectations of future capability to counter pest problems.

6.7.2. The EPA staff also noted that there may be a social benefit from the continued use of CCD in that it may be cheaper than alternative substances.

6.7.3. The Committee considered that these positive effects result in tangible benefits to society and communities.

7. Assessment of adverse effects

7.1. Summary

7.1.1. Carbaryl, chlorpyrifos and diazinon, being a carbamate and organophosphates, are known to be toxic to people and the environment. The mode of action by which they kill pests (inhibition of the acetylcholinesterase enzyme) also affects humans and other species. The generic effects of OPCs have been discussed in the EPAs decision on the reassessment of OPCs (APP202142) and are also relevant here.

7.2. Risk Assessment

7.2.1. EPA staff undertook a human health and environmental risk assessment for CCD-containing substances in use in New Zealand.

7.2.2. The data relating to the toxicological and ecotoxicological effects are based on human or animal studies. Where possible, the toxicity and ecotoxicity data specific to the substances evaluated are those used by other international regulators. In some instances key information relevant to the risk assessment, such as higher tier operator or re-entry worker exposure monitoring studies or dermal absorption data were not available. In these instances, EPA staff followed international practice and used reasonable worst case scenarios or default values, or did not calculate the risks.

7.2.3. Exposure was assessed using application rates and methods provided by stakeholder feedback including additional information from Orion Crop Protection Ltd about the use pattern of TopClip, as well as the application rates and methods listed on product labels.

7.2.4. To allow a comparison between the benefits and the risks associated with the application of CCD-containing substances, qualitative descriptors were used which assign the level of risk into broad categories of negligible, low, medium or high. In line with the EPA's Methodology, these descriptors account for the likelihood and magnitude of an adverse effect. The Committee considered that even low risks are of concern.

7.2.5. Full details on the risk assessment approach and results can be found in the application and the EPA staff update report.

7.3. Adverse effects on human health

7.3.1. The Committee considered the effects on human health outlined in the application and further refined in the Staff Update Report. The Committee noted that use of these substances, with the exception of carbaryl based ear drops, presents risks to human health that are significantly higher than an acceptable level of concern.

7.3.2. The Committee questioned the fact that the Australian Pesticides and Veterinary Medicines Authority's review of the adverse effects of flea collars on human health showed no risks to human health. EPA staff responded that there appeared to be no quantitative risk assessment included in that Australian review. The review appeared to assume that diazinon stays in the

collar matrix and didn't consider the same exposure pathways that EPA staff factored into the EPA risk assessment.

7.3.3. The Committee considered the adverse effects on human health to be non-negligible.

Acute poisoning

7.3.4. The acute effects of exposure to high levels of CCD are well established from animal studies and numerous human poisoning incidents.

7.3.5. Short term exposure can result in symptoms including increased sweating and salivation, dizziness, fatigue, runny nose or eyes, nausea, intestinal discomfort, confusion and changes in heart rate. At high levels of exposure more severe effects such as paralysis, seizures, loss of consciousness and death may occur.

7.3.6. In addition to the immediate effects, there are a number of possible neurological complications that can develop in the subsequent days-weeks following initial recovery: Intermediate syndrome (IMS) and OP-Induced Delayed Polyneuropathy (OPIDP).

7.3.7. The Committee noted that there is a paucity of data on CCD poisoning incidents in New Zealand. The extent of acute poisoning relating to organophosphates (let alone CCD) in non-plant protection use is unknown. However, the Committee was not convinced that the relative lack of reported cases is representative of the level of acute poisoning in New Zealand. The symptoms of CCD poisoning are non-specific and the time of onset varies depending on the route and severity of exposure. The Committee therefore considered under-recognition and under-reporting likely.

Chronic health effects

7.3.8. As well as acute toxicity, concerns have been raised over the potential for longer term adverse health effects. This includes the potential for chronic health effects following acute poisoning and for effects as a result of chronic exposure to low levels that do not cause the clinical signs or symptoms of poisoning.

7.3.9. Animal and human epidemiological studies have reported associations between acute and/or chronic exposure and a number of adverse effects. Examples of the type of effects that have been raised as concerns are:

- Neuropsychological effects e.g. on attention, perception and memory
- Effects on motor function and muscle coordination
- Effects on the development of the nervous system following pre-natal or childhood exposure
- Psychiatric illness e.g. anxiety and depression
- Parkinson's disease
- Increased risk of cancer
- Increased risk of obesity and diabetes.

7.4. Adverse effects on the environment

7.4.1. Carbaryl, chlorpyrifos and diazinon are all harmful to living organisms in the environment, not only to target insects. They are all considered very toxic to some aquatic life and to terrestrial invertebrates (e.g. bees), and in general to birds.

7.5. Adverse effects on the relationship of Māori to the environment

7.5.1. Diazinon in sheep dip may cause major health effects on those handling dip, sheep or from residues in wool, and has the potential to generate major adverse effects on Te Marae o Tangaroa. Diazinon sheep dip is especially likely to be of interest to Māori due to the potential for this substance to enter waterbodies and adversely affect culturally significant food species such as tuna (freshwater eels), inanga (whitebait), kōura / kēwai (freshwater crayfish) and piharau (lamprey). Furthermore, Māori are highly represented in occupations that involve handling sheep or wool (e.g. farming and shearing) whereby they may be exposed to diazinon. The foregoing risks to Māori associated with diazinon are elevated because there are no practical controls that can be applied to adequately manage potential risk to people and/or the environment.

7.6. Adverse effects on society and communities

7.6.1. In addition to human health effects or discrete incidents of harm to the environment, the Committee considered that there is a broader adverse effect associated with the use of CCD-containing substances which results from general social concern and anxiety associated with their use.

7.7. Withdrawal of products from the market.

7.7.1. Many of the substances listed in the application have already been voluntarily withdrawn from the market. The Committee considers that there will be no adverse effects to New Zealand if these products are no longer approved for import and manufacture in New Zealand. Furthermore, the Committee is aware that there are alternative products available for use.

8. International obligations

8.1.1. To achieve the purpose of HSNO, the EPA must consider the impacts of the application on New Zealand's international obligations.

8.1.2. The EPA staff have identified that all OPCs must meet the World Health Organization/Food and Agriculture Organisation Joint Meeting on Pesticide Specifications (JMPS) standards. Carbaryl, chlorpyrifos and diazinon are covered under this obligation despite their uses in veterinary medicines and for other non-plant protection uses.

9. Overall evaluation of effects

9.1. Introduction

9.1.1. The overall evaluation of risks, costs and benefits was carried out having regard to the tests in clauses 26 and 27 of the Methodology and section 29 of the Act.

9.1.2. Clause 34 of the Methodology sets out the approaches available to the Authority in evaluating the combined impact of risks, costs and benefits i.e. weighing up the risks, costs and benefits.

9.2. Summary and conclusions

9.2.1. The Committee considers that the risks from using Fido's Ear Drops are negligible after the controls are applied, and that the benefits are non-negligible. The Committee therefore considered this substance via clause 26 of the Methodology. The Committee considered that the benefits outweigh the risks.

9.2.2. The Committee considered that the risks associated with the use of TopClip are non-negligible and that there are no controls that would mitigate the risks. The Committee considered that the benefits from use of this product are negligible. The Committee therefore considered this substance via clause 27 of the Methodology, and the Committee considered that the risks outweigh the benefits.

9.2.3. The Committee considered the risks associated with the use of diazinon in flea collars for cats and dogs are non-negligible and that the benefits are negligible. The Committee considered their decision via clause 27 of the Methodology, and considered that the risks outweigh the benefits.

9.2.4. For all other substances listed in the application, the Committee noted that these have been withdrawn voluntarily from the market. The Committee considered the risks from these substances to be non-negligible and the benefits to be negligible. The Committee considered these substances via clause 27 of the Methodology and considered that the risks associated with all these substances outweigh the benefits of these products.

10. Decision

10.1.1. Pursuant to Part 2 of the Act, and to sections 63 and 29 of the Act, the Committee has considered this application to reassess CCD for use in veterinary medicines and for non-plant protection uses.

10.1.2. Based on consideration and analysis of the information provided, and in accordance with the Act and the Methodology, and taking into account the application of the default controls and the varied and additional controls, the Committee is satisfied, for the reasons set out in this decision, that the positive effects (benefits) associated with the use of the substances covered in this application do not outweigh the adverse effects (risks and costs), with the exception of one approval (HSR001825 – Fido's Ear Drops).

10.1.3. For all other approvals, the Committee has decided that the adverse effects cannot be mitigated by use of additional controls, and that the adverse effects outweigh any potential benefits. The Committee has also considered the likely effects of the substances being unavailable and decided to decline the approvals. All approvals for substances identified in this document are therefore declined, other than approval HSR001825 (Fido's Ear Drops).

10.1.4. EPA staff recommended a phase out for products which have been declined. However, the Committee considered that for all declined approvals, the decision will take effect on February 28 after a notice issued in accordance with section 66 of the Act is published in the Gazette ("the commencement date"). That notice specifies the controls relating to the use / disposal of the substance for 3 years.

10.1.5. The effect of this decision is that:

- Import/manufacture is no longer authorised on the commencement date of the notice: and
- Use to be prohibited 3 years from the commencement date to allow use of existing stocks of TopClip and flea collars.

10.1.6. The application for importation and manufacture of Fido's Eardrops, where the positive effects outweigh the adverse effects is approved, with the controls listed in Appendix D of this document. The Committee decided that the benefits outweigh the risks, and confirmed that the controls mitigate any potential adverse effects. The Committee has provided for the continuation of carbaryl ear drops with a 2 year phase in period of the new controls to allow time for new labels and packages to be developed and implemented.

Deborah Read	**26 January 2016**
Chair, Decision Making Committee	**Date:**

Appendix A: Decision path for the reassessment of CCD

Context

This decision path describes the decision-making process for the application to import or manufacture CCD and its formulations. This application is made under section 63 (Reassessment) of the HSNO Act, and determined under section 29 of the Act.

Introduction

The purpose of the decision path is to provide the HSNO decision maker[2] with guidance so that all relevant matters in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the HSNO decision maker may decide to make on individual aspects of an application.

In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the Methodology.

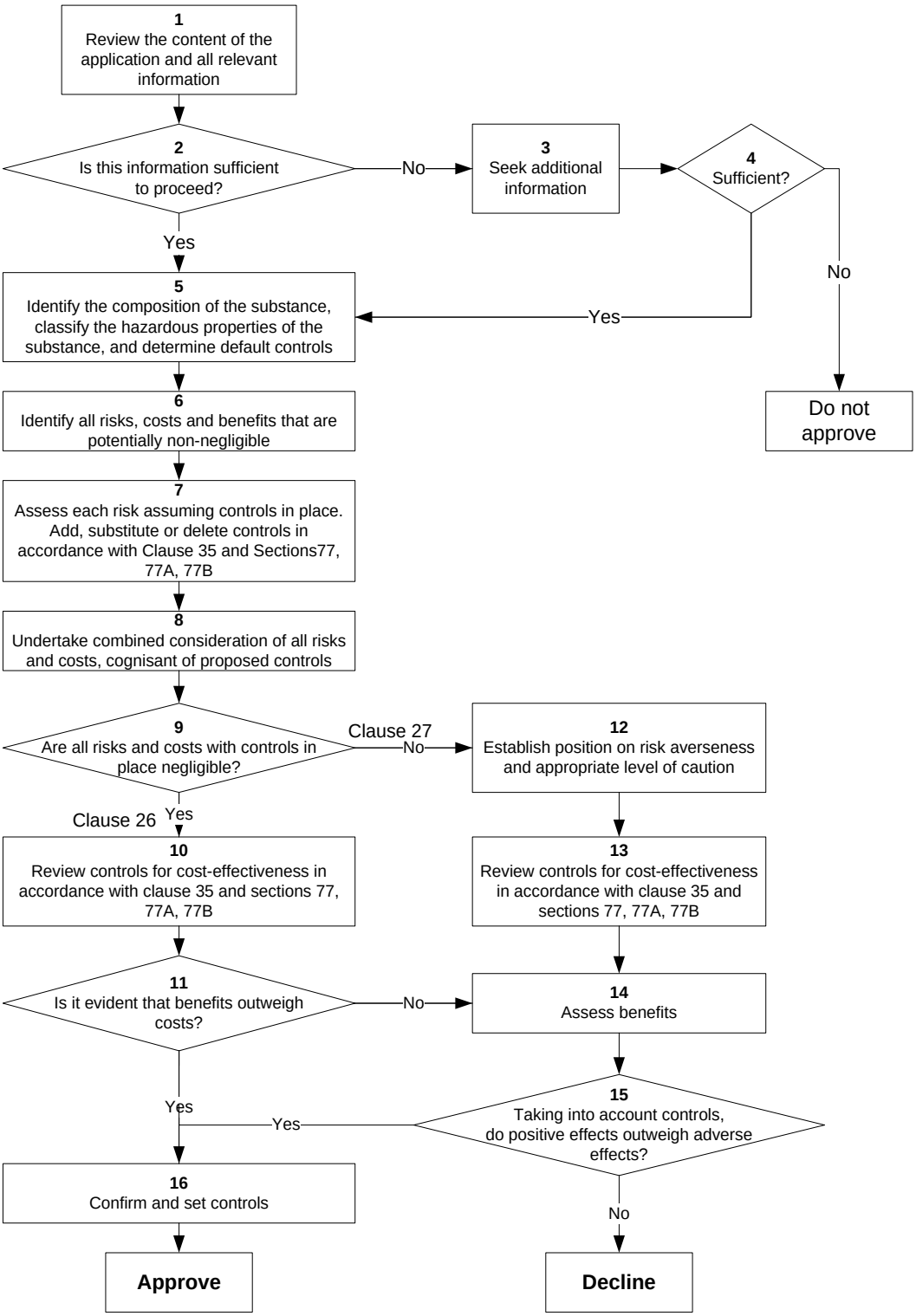
The decision path has two parts –

- Flowchart (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and
- Explanatory noted (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory note provide a more comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

[2] The HSNO decision maker refers to either the EPA Board or any committee or persons with delegated authority from the Board.

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



Explanatory Noted

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.
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. The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; i.e. information which is "necessary and sufficient" for decision-making.
Item 3:	**(if 'no' from item 2) Seek additional information** If there is not sufficient information then additional information may need to be sought from the applicant, the EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).
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 must be declined under section 29(1)(c).
Item 5:	**(If 'yes' from item 2 or from item 4) Identify the composition of the substance, classify the hazardous properties, and determine default controls** Identify the composition of the substance, and establish the hazard classifications for the identified substance. Determine the default controls for the specified hazardous properties using the regulations 'toolbox'.
Item 6:	**Identify all risks, costs and benefits that are potentially non-negligible**[3] Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 11). Identification is a two-step process that scopes the range of possible effects (risks, costs and benefits).

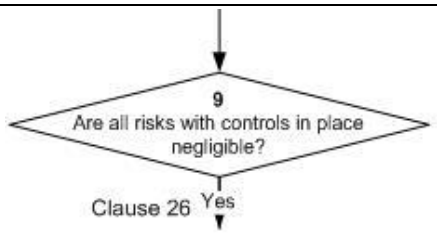
[3] Relevant effects are **marginal effects**, or the changes that will occur as a result of the substance being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the substance(s) and are therefore not taken into account 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.

	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[4]. 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[5], 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 it 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 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[6]. 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	

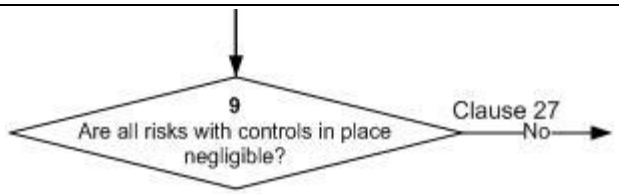
[4] Effects on the natural environment, effects on human health and safety, effects on Māori culture and traditions, effects on society and community, effects on the market economy.

[5] 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.

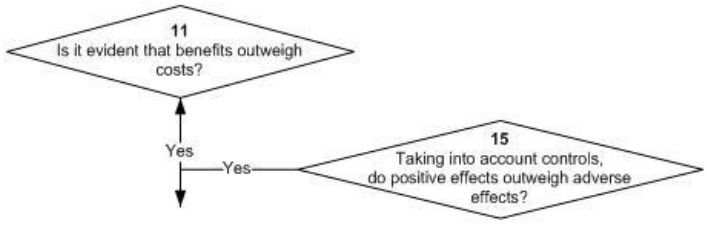
[6] http://www.epa.govt.nz/Publications/Approach-to-Risk.pdf

	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 10 and 13 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:	**Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a 'basket' of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.
Item 9:	**Are all risks with controls in place negligible?** Looking at individual risks in the context of the 'basket' of risks, consider whether all of the residual risks are negligible.
Item 10:	 **(from item 9 - if 'yes') 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 practicality and cost-effectiveness of the proposed individual controls and exposure limits (clause 35). 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 11:	**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[7]. 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 14).

[7]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'.

Item 12:	 **(if 'no' from item 9) Establish 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 13:	**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 9 and 12). Consider whether any of the non-negligible risks can be reduced by varying the controls in accordance with sections 77 and 77A of the Act, or whether there are available more cost-effective controls that achieve the same level of effectiveness (section 77A(4)(b) and clause 35(a)). Where relevant and appropriate, add, substitute or delete controls whilst taking into account the views of the applicant (clause 35(b)), and making sure that the total benefits that result from doing so continue to outweigh the total risks and costs that result. As for item 7, if the substance has toxic or ecotoxic properties, consider exposure limits under section 77B.
Item 14:	**(if 'no' from item 11 or in sequence from item 13) 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 it 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[8]. 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 15:	**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

[8] This principle derives from Protocol Series 1, and is restated in the Technical Guide 'Decision making'.

	ranking of risks. The weighing up process takes into account controls proposed in items 5, 7, 10 and/or 13. Where this item is taken in sequence from items 12, 13 and 14 (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 9, 10, 11 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.
Item 16:	 **(if 'yes' from items 11 or 15) Confirm and set controls** Controls have been considered at the earlier stages of the process (items 5, 7, 10 and/or 13). The final step in the decision-making process brings together all the proposed controls, and reviews for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

Appendix B Draft direction under section 66 of the Act

Hazardous Substances (Carbaryl, Chlorpyrifos and Diazinon Direction Prohibiting Use and Controlling Storage and Disposal) Notice 2015

Pursuant to section 66 of the Hazardous Substances and New Organisms Act 1996 ("the Act"), the Environmental Protection Authority issues the following notice.

N o t i c e

1. Title—

This notice is the Hazardous Substances (Carbaryl, Chlorpyrifos and Diazinon Containing Substances Direction Prohibiting Use and Controlling Storage and Disposal) Notice 2016.

2. Commencement—

This notice comes into force on 28 February 2016.

3. Interpretation—

(1) In this notice, words and phrases have the meanings given to them in the Act and in Regulations made under the Act.

(2) In this notice, the following words have the following meanings:

Carbaryl means carbaryl (CAS Number 63-25-2).

Chlorpyrifos means chlorpyrifos (CAS Number 2921-88-2)

Diazinon means diazinon (CAS Number 333-41-5).

Substances containing carbaryl, chlorpyrifos or diazinon means any of the following substances:

Flammable liquid containing 7 – 13 g/L chlorpyrifos and 100 – 120 g/L cypermethrin, formerly approved under the Act with approval number HSR001812 with the hazards 3.1D, 6.1D (All), 6.1D (O), 6.1E (D), 6.3B, 6.4A, 6.5B, 6.8B, 6.9A (All), 6.9A (O), 9.1A (A), 9.1A (All), 9.1A (C), 9.1A (F), 9.3C, 9.4A;

Flammable liquid containing 120 - 180 g/L chlorpyrifos, formerly approved under the Act with approval number HSR001814 with the hazard classification 3.1D, 6.1C (All), 6.1C (D), 6.1D (O), 6.3B, 6.4A, 6.7B, 6.9A (All), 9.1A (A), 9.1A (All), 9.1A (C), 9.1A (F), 9.2C, 9.3B, 9.4A;

Flammable liquid containing 32 – 50% chlorpyrifos formerly approved under the Act with approval number HSR001816 with the hazard classification 3.1D, 6.1C (All), 6.1C (D), 6.1C (O), 6.3A, 6.7B, 6.8B, 6.9A (All), 6.9A (O), 8.3A, 9.1A (A), 9.1A (All), 9.1A (C), 9.1A (F), 9.2B, 9.3A, 9.4A;

Collar containing 140 - 180 g/kg diazinon and 1.7 - 3.2 g/kg pyriproxyfen formerly approved under the Act with approval number HSR001802 with the hazard classification 6.4A, 9.1A (All), 9.1A (C), 9.1A (F), 9.1B (A), 9.4A;

Collar containing 140 - 180 g/kg diazinon formerly approved under the Act with approval number HSR001807 with the hazard classification 6.4A, 9.1A (All), 9.1A (F), 9.1B (A), 9.1B (C), 9.4A;

Flammable liquid containing 360 - 440 g/litre diazinon formerly approved under the Act with approval number HSR001953 with the hazard classification 3.1D, 6.1D (All), 6.1D (D), 6.1D (I), 6.1D (O), 6.3B, 6.4A, 6.7B, 6.8B, 6.9A (All), 9.1A (All), 9.1A (C), 9.1A (F), 9.1C (A), 9.2D, 9.3A, 9.4A;

Solid containing 20 – 50 g/kg diazinon formerly approved under the Act with approval number HSR001808 with the hazard classification 6.4A, 6.8B, 6.9B (All), 9.1A (All), 9.1A (C), 9.1A (F), 9.3A, 9.4A;

Flammable liquid containing 0.26 – 5% diazinon formerly approved under the Act with approval number HSR002288 with the hazard classification 3.1C, 6.1D (All), 6.1D (I), 6.1D (O), 6.3A, 6.6B, 6.8B, 8.3A, 9.1A (All), 9.1A (C), 9.1A (F), 9.1B (A), 9.3B, 9.4B;

Dustable powder containing 50 g/kg carbaryl formerly approved under the Act with approval number HSR000672 with the hazard classification 6.1E (All), 6.1E (O), 6.7B, 6.9B (All), 9.1B (All), 9.1B (C), 9.4C;

Wettable powder containing 800 g/kg carbaryl formerly approved under the Act with approval number HSR000819 with the hazard classification 6.1C (All), 6.7B, 6.9B (All), 9.1A (All), 9.2B, 9.3B, 9.4A;

Ready to use bait containing 5 g/kg chlorpyrifos formerly approved under the Act with approval number HSR000164 with the hazard classification 9.1A (All), 9.1A (C), 9.1A (F), 9.3C, 9.4B;

Paste containing 5 g/kg chlorpyrifos formerly approved under the Act with approval number HSR000166 with the hazard classification 6.5B, 9.1A (All), 9.1A (C), 9.1A (F), 9.3C, 9.4B;

Microencapsulated suspension concentrate containing 200 g/L chlorpyrifos formerly approved under the Act with approval number HSR000168 with the hazard classification 6.9A (All), 9.1A (A), 9.1A (All), 9.1A (C), 9.1A (F), 9.2C, 9.3B, 9.4A;

Emulsifiable concentrate containing 240 g/litre chlorpyrifos formerly approved under the Act with approval number HSR000169 with the hazard classification 3.1C, 6.1C (All), 6.1C (D), 6.1C (O), 6.3A, 6.4A, 6.8B, 6.9A (All), 9.1A (A), 9.1A (All), 9.1A (C), 9.1A (F), 9.2C, 9.3B, 9.4A;

Ready to use liquid containing 20 g/litre chlorpyrifos formerly approved under the Act with approval number HSR000172 with the hazard classification 3.1C, 6.1D (All), 6.1D (O), 6.3B, 6.4A, 6.5B, 6.7B, 6.9B (All), 9.1A (All), 9.1A (C), 9.1A (F), 9.2B, 9.3B, 9.4B;

Flammable liquid containing 2.5 – 3% chlorpyrifos formerly approved under the Act with approval number HSR001810 with the hazard classification 3.1C, 6.1D (All), 6.1D (O), 6.1E (D), 6.3A, 6.8B, 6.9B (All), 8.3A, 9.1A (All), 9.1A (C), 9.1A (F), 9.2C, 9.3B, 9.4A;

General purpose insect spray (contains diazinon) formerly approved under the Act with approval number HSR001741 with the hazard classification 6.1E (All), 6.1E (O), 6.3B, 6.4A, 6.8B, 6.9B

(All), 6.9B (D), 6.9B (I), 6.9B (O), 9.1A (All), 9.1A (C), 9.1A (F), 9.1C (A), 9.3A, 9.4A;

Aerosol containing 0.3 – 0.7% carbaryl and 0.4 – 0.8% piperonyl butoxide formerly approved under the Act with approval number HSR001811 with the hazard classification 6.1D (All), 6.1D (O), 6.3A, 6.4A, 6.7B, 6.8B, 6.9A (All), 9.1C (All), 9.1C (C), 9.1C (F), 9.3C, 9.4C.

4. Prohibition on use—

(1) No person may use a substance containing carbaryl, chlorpyrifos or diazinon after 3 years hence.

5. Controls on substances containing carbaryl, chlorpyrifos and diazinon until 3 years hence.—

(1) The substances containing carbaryl, chlorpyrifos or diazinon are deemed to have the hazard classifications as specified in the definition in 3(2) of this notice.

(2) Unless otherwise specified below, the controls set out for the approvals specified in this notice shall apply to the substances containing carbaryl, chlorpyrifos or diazinon].

(3) For the purposes of Regulation 10 of the Hazardous Substances (Class 6, 8, and 9 Controls) Regulations 2001, no substances containing carbaryl, chlorpyrifos or diazinon in any quantity may be carried on any passenger service vehicle.

6. Controls on the disposal of substances containing carbaryl, chlorpyrifos or diazinon—

(1) All substances containing carbaryl, chlorpyrifos or diazinon must be disposed of by 28 February 2019.

(2) Substances containing carbaryl, chlorpyrifos or diazinon must be disposed of in accordance with the Hazardous Substances (Disposal) Regulations 2001, excluding regulations 8(1)(b) or 9(1)(b).Therefore, substances containing carbaryl, chlorpyrifos or diazinon must not be disposed of by discharge into the environment.

(3) When stored for the purpose of disposal, substances containing carbaryl, chlorpyrifos or diazinon must not be mixed with any other substance.

Dated at Wellington this 28th day of February 2016.

For and on behalf of the Environmental Protection Authority:

xxxxxxxxxxxx.

Appendix C: Abbreviations and acronyms

Term	Definition
Acute	Adverse effect that occurs after a single exposure which usually lasts for a short time.
ADE	Acceptable Daily Exposure is the amount of a substance that an individual can be exposed to daily over a lifetime without resulting in an appreciable toxic effect.
ADI	Acceptable Daily Intake is the amount of a substance in food or drinking water that can be ingested daily over a lifetime without an appreciable health risk.
Approved Handler	A person who holds a current test certificate certifying that the person has met the requirements of Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001 in relation to an approved handler for 1 or more hazard classifications or hazardous substances.
Benefit	The value of a positive effect expressed either in monetary or non-monetary terms.
Chronic	Adverse effect that occurs after a repeated exposure and which usually are long lasting and recurring.
Cost	The value of an adverse effect expressed either in monetary or non-monetary terms.
Endpoint	Toxicological or ecotoxicological value used in the risk assessment
Exposure	Human or environmental organism contact with a substance.
GAP	Good Agricultural Practice. GAP is an internationally recognised food safety tool for describing best practice for safe and effective chemical use.
HSNO	The Hazardous Substances and New Organisms Act 1996.
IPM	Integrated Pest Management involves the careful use of pest control techniques to discourage the development of pest populations and minimises the use of pesticides.
Likelihood	The probability of an effect occurring.
Magnitude	Expected level of effect.
MPI	Ministry for Primary Industries
MRL	Maximum Residue Limits restrict the quantity of a given chemical remaining on food product samples, which is acceptable in a specific market.
PDE_{food}	The Potential Daily Exposure for food is the amount of a substance in food which may be ingested daily over a lifetime without resulting in an appreciable toxic effect.
Phytosanitary	Relates to the health of plants, especially with respect to the requirements of international trade.
PPE	Personal Protective Equipment including any item of equipment used to protect a person from hazards e.g. safety helmet, goggles, gloves, boots, respirator.
REI	A Restricted Entry Interval is the time which must elapse after application of a substance before entry into the treated area is permitted without use of PPE or Respiratory Protective Equipment.
RPE	Respiratory Protective Equipment (a type of PPE).
Risk	The combination of the magnitude of an adverse effect and the probability of its occurrence.

Appendix D: Controls for the carbaryl containing substance Fido's Eardrops (HSR001825)

The Committee have amended the existing suite of controls applied to this substance as a consequence of the changes to default and additional controls relevant for this veterinary medicine, as detailed in this application. The following tables detail the controls for this substances. Changes are highlighted where new controls or variations are in place, and include dates when the changes come into effect.

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
T1	Regs 11 – 27	Limiting exposure to toxic substances through the setting of TELs	**Tolerable Exposure Limits** No tolerable exposure limit (TEL) is set for this substance at this time
T2	Regs 29, 30	Controlling exposure in places of work through the setting of WESs	
T4	Reg 7	Requirements for equipment used to handle substances	
T5	Reg 8	Requirements for protective clothing and equipment	
T7	Reg 10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles	**Regulation 10 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001** This regulation applies to this substance, as if each item in Schedule 2 of the regulations relating to the specified hazard classification was replaced by:

Hazard Classification	Liquid (L)	Solid (kg)
6.5B	1	3

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
E1	Regs 32 – 45	Limiting exposure to ecotoxic substances through the setting of EELs	**Regulation 32 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001** Regulation 32 sub clauses (1) and (2) are deleted

Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	Regs 6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	
I3	Reg 9	Priority identifiers for ecotoxic substances	**Regulation 9 of the Hazardous Substances (Identification) Regulations 2001** This regulation applies to this substance as if regulation 9 was replaced by: A hazardous substance must be identified by an indication that it is ecotoxic when the amount of the substance contained in a package is greater than or equal to 100 ml
I9	Reg 18	Secondary identifiers for all hazardous substances	
I11	Reg 20	Secondary identifiers for ecotoxic substances	**Regulation 20 of the Hazardous Substances (Identification) Regulations 2001** This regulation applies to this substance as if, after the word “substance” in the second line, the following were inserted: when the amount of the substance contained in a package is greater than or equal to 100 ml
I16	Reg 25	Secondary identifiers for	

		toxic substances	
I17	Reg 26	Use of generic names	
I18	Reg 27	Requirements for using concentration ranges	
I19	Regs 29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I21	Regs 37 – 39, 47 – 50	General documentation requirements	
I23	Reg 41	Specific documentation requirements for ecotoxic substances	
I28	Reg 46	Specific documentation requirements for toxic substances	
I29	Regs 51, 52	Signage requirements	

Hazardous Substances (Packaging) Regulations 2001

Code	Regulation	Description	Variation
P1	Regs 5, 6, 7(1), 8	General packaging requirements	
P3	Reg 9	Criteria that allow substances to be packaged to a standard not meeting	

		Packing Group I, II or III criteria	
P13	Reg 19	Packaging requirements for toxic substances	**This variation takes effect on 1 January 2018.** **Regulation 19 Packaging requirements for toxic substances (class 6)** Sub clauses (2) and (3) are replaced by the following: (2) Packaging for this substance that is offered for sale must be child resistant. (3) No person can supply this substance to any other person unless the substance is in a package that is child resistant. (4) Sub clauses (2) and (3) do not apply if— (a) the offer for sale is made in respect of a place of work to which children do not have access; and (b) the substance is for use in that place of work.
P15	Reg 21	Packaging requirements for ecotoxic substances	**This control takes effect on 1 January 2018.**
PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III	**This control takes effect on 1 January 2018.**
PS4	Schedule 2	Packaging requirements as specified in Schedule 4	

Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D4	Reg 8	Disposal requirements for toxic and corrosive substances	
D5	Reg 9	Disposal requirements for ecotoxic substances	

D6	Reg 10	Disposal requirements for packages	
D7	Regs 11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge	
D8	Regs 13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge	

Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	Regs 6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM6	Reg 8(e)	Information requirements for toxic substances	
EM7	Reg 8(f)	Information requirements for ecotoxic substances	**Regulation 8(f) of the Hazardous Substances (Emergency Management) Regulations 2001** This regulation applies to this substance as if, after sub clause (f), the following sub clause was inserted: (fa) Sub clause (f) shall only apply if the amount of the substance contained in a package is greater than or equal to 100 ml or 100 g
EM8	Regs 12 – 16, 18 – 20	Level 2 information requirements for suppliers	

		and persons in charge	
EM11	Regs 25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM12	Regs 35 – 41	Level 3 emergency management requirements: secondary containment	**Regulation 36 of the Hazardous Substances (Emergency Management) Regulations 2001** The following sub clauses are added after sub clause (3) of regulation 36: *(4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of containment in the pipework it—* *(a) is not to be taken into account in determining whether a place is required to have a secondary containment system; and* *(b) is not required to be located in a secondary containment system.* *(5) In this clause, pipework—* *(a) means piping that—* *(i) is connected to a stationary container; and* *(ii) is used to transfer a hazardous substance into or out of the stationary container; and* *(b) includes a process pipeline or a transfer line.*
EM13	Reg 42	Level 3 emergency management requirements: signage	

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Code	Regulation	Description	Variation
Tank Wagon	Regs 4 to 43 as applicable	Controls relating to tank wagons and transportable containers	

Additional controls

Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004

Code	Regulation	Description	Variation
Sch 8	Schedule 8	This schedule prescribes the controls for stationary container systems. The requirements of this schedule are detailed in the consolidated version of the Hazardous Substances (Dangerous Goods and Schedule Toxic Substances) Transfer Notice 2004, available from http://www.epa.govt.nz/Publications/Transfer-Notice-35-2004.pdf	The controls relating to stationary container systems, secondary containment and unintended ignition of flammable substances, as set out in Schedules 8, 9 and 10 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (Supplement to the New Zealand Gazette, 26 March 2004, No. 35, page 767), as amended, shall apply to this substance, notwithstanding clause 1(1) of Schedules 8 and 9 and clause 1 of Schedule 10
Use restriction	S77A	**The following control takes effect on 1 January 2018:** No person can apply this substance for any purpose other than as a veterinary medicine	
Labelling	S77A	**The following control takes effect on 1 January 2018:** A person must not supply this substance to any other person unless the substance label clearly states that— (a) access to the substance by children must be restricted, such as “Keep out of reach of children”; and (b) users should wear gloves when handling the substance.	