



Australian Government  
Australian Pesticides and  
Veterinary Medicines Authority



# CARBARYL

Part 2: Uses of carbaryl in agricultural situations

VOLUME 1: FINAL REVIEW REPORT AND REGULATORY DECISION

Reconsideration of registration of products containing carbaryl  
and approvals of their associated labels

AUGUST 2012

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## FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority responsible for regulating agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA can reconsider the approval of an active constituent, the registration of a chemical product or the approval of a label for a container for a chemical product at any time. This is outlined in Part 2, Division 4 of the Agvet Codes.

Reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label.

The reconsideration process includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

In undertaking reconsiderations (here referred to as 'reviews'), the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety in the Department of Health and Ageing, the Department of the Environment, Water, Heritage and the Arts, and state departments of agriculture, as well as other expert advisers as appropriate.

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision making. The publication of review reports is a part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries under bilateral agreements. The APVMA recommends that countries receiving these reports will not use them for registration purposes unless they are also provided with the raw data from the relevant applicant.

The basis for the current reconsideration is whether the APVMA is satisfied that the continued use of products containing carbaryl in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, and/or
- would not be likely to have an effect that is harmful to human beings.

The APVMA also considered whether product labels carry adequate instructions and warning statements.

This document is *Reconsideration of registrations of products containing carbaryl and their associated labels. Final Review Report and Regulatory Decision Part 2: Uses of carbaryl in agricultural situations* and relates to all products containing carbaryl used in agricultural situations that were nominated for review by the APVMA. The review's findings and regulatory decision are based on information and technical data collected from a variety of sources.

The Final Review Report and Regulatory Decision containing the APVMA's assessments for all registrations and approvals relating to carbaryl used in agricultural situations (the APVMA Review of Carbaryl—Part 2) and the technical reports are available from the APVMA website:

[www.apvma.gov.au/chemrev/chemrev.html](http://www.apvma.gov.au/chemrev/chemrev.html).

## ACRONYMS, ABBREVIATIONS AND DEFINITIONS

<b>ADI</b>	The <b>Acceptable Daily Intake</b> of a chemical is defined as the daily intake that during an entire lifetime, appears to be without appreciable risk, on the basis of the information available at the time of the assessment. It is expressed in milligrams of the chemical per kilogram of bodyweight per day (mg/kg bw/d). 'Without appreciable risk' means that adverse effects will not result even after a lifetime of exposure.
<b>APVMA</b>	The <b>Australian Pesticides and Veterinary Medicines Authority</b> is the Australian government authority responsible for the assessment and registration of pesticides and veterinary medicines and for their regulation up to and including the point of retail sale.
<b>ARfD</b>	The <b>Acute Reference Dose</b> is the estimated amount of a substance in food or drinking water, expressed on a bodyweight basis that can be ingested over 24 hours or less, without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation.
<b>bw</b>	<b>Body weight.</b>
<b>ChE</b>	<b>Cholinesterase</b> is an enzyme of the body necessary for proper nerve function.
<b>Codex</b>	The <b>FAO/WHO Codex Alimentarius Commission</b> is a body set up by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It coordinates input from more than 160 countries to develop and endorse the standards that comprise the international food code. Codex standards are a global reference point for international food trade.
<b>DFR</b>	<b>Dislodgeable foliar residues</b> represent chemical residues on the surfaces of treated foliage that are available for transfer to exposed populations (for example, workers entering treated crops) during contact with those treated leaf surfaces. That is, DFRs are the amount of chemical residues deposited on the leaf surface that have not been absorbed into the leaf or dissipated from the surface, and that can be dislodged.
<b>DIAMOND</b>	<b>Dietary Modelling Of Nutritional Data</b> is a program used by FSANZ for the dietary exposure assessment calculations using statistical software provided by software company SAS.
<b>DNA</b>	<b>Deoxyribonucleic acid</b> is a double-stranded, helical nucleic acid molecule that carries genetic information.
<b>FAISD Handbook</b>	The <b>First Aid Instructions and Safety Directions Handbook</b> is the <i>Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals</i> published by the Office of Chemical Safety in the Australian Government Department of Health and Ageing.
<b>FAO</b>	The <b>United Nations Food and Agriculture Organization</b> is the international agency established to help raise levels of nutrition and standards of living, to secure improvements

in the efficiency of the production and distribution of food and agricultural products, and to better the condition of rural populations.

- FSANZ** **Food Standards Australia New Zealand** is a bi-national independent statutory authority that develops food standards for composition, labelling and contaminants, including microbiological limits, which apply to all foods produced or imported for sale in Australia and New Zealand.
- GAP** **Good agricultural practice** is the recommended or registered use pattern of a chemical product that is necessary for effective and reliable pest control.
- HAL** **Horticulture Australia Limited** is a national research, development and marketing organisation that works in partnership with the horticulture sector to invest in programs that provide benefit to Australian horticultural industries.
- IRED** The **Interim Reregistration Eligibility Decision** is the US EPA report that identifies the various conditions and risk mitigation measures necessary to ensure that approved uses of a pesticide meet United States safety standards.
- JMPR** The **Joint FAO/WHO Meeting on Pesticide Residues** is an international expert scientific group that is administered jointly by the FAO and the WHO. The JMPR is responsible for reviewing the toxicology, residues and analytical aspects of pesticides.
- LC<sub>50</sub>** The **median lethal concentration** is the dose of a toxicant that will kill 50% of test organisms within a designated period of time. The lower the LC<sub>50</sub>, the more toxic the compound. 'LC' usually refers to a concentration of the chemical in air.
- LD<sub>50</sub>** The **median lethal dose** is the dose of a toxicant that will kill 50% of test organisms within a designated period of time. The lower the LD<sub>50</sub>, the more toxic the compound.
- LOEL** The **Lowest Observed Effect Level** is the lowest dose of a substance to cause changes distinguishable from those observed in normal (that is, control) animals (WHO, 1990).
- MOE** The **margin of exposure** is the ratio of the no-observed adverse-effect-level (NOEL) to the estimated exposure dose. This is the safety margin that measures the difference between the highest amount of chemical that the OCS estimates will *not* cause an adverse effect in laboratory test species, and the dosage of chemical that the OCS estimates a worker may be exposed to per day. An MOE of 100 or more, when the NOEL is based on a toxicity study in animals, is generally considered to be acceptable.
- MRL** **Maximum residue limit** means the maximum concentration of a residue that is legally permitted or recognised as acceptable in or on a food or agricultural commodity.
- NEDI** The **National Estimated Daily Intake** is an estimate of dietary exposure to a particular pesticide residue. It uses national food consumption data including those for specific subgroups of the population. The NEDI calculation may take into account such factors as the proportion of the crop or commodity treated, residues in edible portions, and the effects of processing and cooking on residue level. Calculations will use median residue levels from

supervised trials, if available. In many cases the NEDI will be an overestimation because actual residue data are not available for many media and hence the MRL is used instead.

- NESTI** The **National Estimated Short-Term Intake** is used to estimate acute dietary exposure. Acute (short-term) dietary exposure assessments are undertaken when an ARfD has been established for a chemical. Acute dietary exposures are normally only estimated based on consumption of raw unprocessed commodities (fruit and vegetables) but may include consideration of meat, offal, cereal, milk or dairy product consumption on a case-by-case basis.
- NOAEL** The **No Observed Adverse Effect Level** is the highest dose of a substance at which no toxic (that is, adverse) effects are observed (WHO, 1990). In more detail: the NOAEL is defined as the highest exposure at which there is no statistically or biologically significant increase in the frequency of an adverse effect when compared to a control group (National Academy of Sciences/National Research Council, 1994). The definition of 'NOEL' is equivalent, but with 'adverse' removed. In considering which of the two terms to use, the issue is often to decide whether a compound-related effect is necessarily adverse.
- NOEC** **No Observed Effect Concentration** (see NOEL).
- NOEL** The **No Observed Effect Level**, or the No-Observable-Effect Level, is the highest dose of a substance administered to a group of experimental animals at which there is an absence of observable effects on morphology, functional capacity, growth, development or life span, which are observed or measured at higher dose levels used in the study. Dosing at the NOEL should therefore produce no biologically significant differences between the group of chemically exposed animals and an unexposed control group maintained under identical conditions. The NOEL is expressed in milligrams of chemical per kilogram of bodyweight per day (mg/kg bw/d) or, in a feeding study, in ppm in food (converted to mg/kg bw of compound intake by measured or estimated food intake over the period of the study). The NOEL has been simply defined as the highest dose of a substance which causes no changes distinguishable from those observed in normal (that is, control) animals (WHO, 1990).
- NSW EPA** The **New South Wales Environment Protection Authority**, a statutory authority formed formerly from part of the previous NSW Department of Environment and Climate Change.  
**DECC** This report uses the current name.
- OCS,** The **Office of Chemical Safety** is part of the Office of Health Protection in the Australian formerly Government Department of Health and Ageing. It is responsible for human health risk  
**OCSEH** assessment policies and practices for veterinary medicines, pesticides and other environmental chemicals. It was previously known as the Office of Chemical Safety and Environmental Health. This report uses the current name.
- OHS** **Occupational health and safety** relates to health and safety issues and actions occurring in a workplace (not domestic issues).
- PCO** A **pest control operator** is a person or company that applies pesticides as a business (for example, exterminator); the term usually describes household services, not agricultural applications.

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<b>PPE</b>	<b>Personal protective equipment</b> is any devices or clothing worn by a worker to protect against hazards in the environment. Examples are respirators, gloves and chemical splash goggles.
<b>ppm</b>	<b>Parts per million</b> denotes the number of parts per 1,000,000 parts, or parts in $10^6$ . For example, 1 mg of impurity in 1 kg of a chemical could be expressed as 1 ppm.
<b>PRF Report</b>	A <b>Preliminary Review Findings Report</b> is a report released by the APVMA that provides the preliminary findings of a chemical review and outlines the proposed regulatory action that may be taken.
<b>QDAFF</b> formerly QDEEDI, QDPIF	<b>Queensland Department of Agriculture, Fisheries and Forestry</b> . It was previously the Queensland Department of Employment, Economic Development and Innovation, and, before that, the Queensland Department of Primary Industries and Fisheries. This report uses the current name.
<b>RBC</b>	A <b>red blood cell</b> is a cell that carries oxygen to all parts of the body. Also called an erythrocyte.
<b>RED</b>	The <b>Reregistration Eligibility Decision</b> is the US EPA report that summarises the decision on a pesticide's eligibility for reregistration.
<b>Re-entry interval</b>	The <b>re-entry interval</b> is the elapsed time determined before workers can safely re-enter crops treated with a pesticide without wearing personal protective equipment.
<b>RfD</b>	The <b>Reference Dose</b> , although considered to be synonymous with 'ADI', is a distinctly defined human health standard set by the US EPA. The RfD is, in general, an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime.
<b>SC</b>	A <b>suspension concentrate</b> is a solution in which the solid active ingredient is dispersed in a liquid (normally water) together with additives, to form a stable water-dispersible suspension. Before application, the concentrate will be mixed with water to achieve the desired spraying dilution.
<b>SUSMP</b> formerly SUSDP	The <b>Standard for the Uniform Scheduling of Medicines and Poisons</b> contains the decisions of the National Drugs and Poisons Scheduling Committee on the classification of medicines and poisons into Schedules. The SUSMP contains certain legal requirements for the labelling of poisons and drugs that are for sale to the public. It was previously known as the Standard for Uniform Scheduling of Drugs and Poisons. This report uses the current name.
<b>TC</b>	The <b>transfer coefficient</b> is the area of leaf surface ( $\text{cm}^2$ ) that it is estimated a worker will come in contact with in an hour of work.
<b>US EPA</b>	The <b>United States Environmental Protection Agency</b> .

- WHO** The **World Health Organization** is the United Nations agency that coordinates international health activities to help national governments improve health services.
- WHP** The **withholding period** is the minimum period of time that must elapse between the last application of an agvet chemical product and the 'use' of the agricultural produce to which the chemical was applied.
- WP** A **wettable powder** is a dry formulation that must be mixed with water or other liquid before it is applied.
- WSP** **Water-soluble packaging** is a special pesticide container or package. Both the package and the pesticide dissolve when the package is dropped into water. Using pesticides in WSP helps protect the mixers from exposure to the chemical.

# CONTENTS

FOREWORD	IV
ACRONYMS, ABBREVIATIONS AND DEFINITIONS	VI
OVERVIEW	XIII
EXECUTIVE SUMMARY	XIV
Introduction	xiv
Review findings	xiv
Final review outcomes	xviii
<b>1 INTRODUCTION</b>	<b>1</b>
1.1 Regulatory status of carbaryl in Australia	1
1.2 Reasons for the carbaryl review	1
1.3 Scope of the review	2
1.4 Regulatory options	3
<b>2 APPROVED CARBARYL USE PATTERNS</b>	<b>5</b>
2.1 Agricultural uses of carbaryl in Australia at the time of the review	5
Tree and vine crops	5
Fruit and vegetable crops	7
Field crops, pastures and stored grain	8
Ornamentals	11
Miscellaneous uses	11
Animal treatment	13
<b>3 SUMMARY OF DATA ASSESSMENTS</b>	<b>14</b>
3.1 Toxicology	14
Introduction	14
Toxicology hazard profile	15
Metabolism and toxicokinetics	17
Cholinesterase inhibition	17
Genotoxicity	18
Neurotoxicity and behavioural studies	18
Reproduction and development	18
Carcinogenicity	18
3.2 Occupational health and safety	19
3.3 Residues and trade	20
Introduction	20
Maximum residue limits for cereal uses	21

Animal feed commodities	21
Animal commodities	22
Dietary intake	23
Changes to Maximum Residue Limits Standards	25
Withholding periods	25
Summary review findings from the assessment of residue data	25
<b>3.4 Overseas regulatory status</b>	<b>28</b>
Joint FAO/WHO Meeting on Pesticide Residues	28
United States Environmental Protection Agency	29
United Kingdom Department of Environment, Food and Rural Affairs report, September 1996	30
European Union	30
<b>3.5 Summary of public submissions</b>	<b>31</b>
General comments	31
Submissions on the residues assessment	31
Submissions on the toxicology and occupational health and safety assessments	33
<b>3.6 Protected data</b>	<b>40</b>
<hr/>	
<b>4 REVIEW OUTCOMES AND REGULATORY DECISIONS</b>	<b>41</b>
<b>4.1 Vary conditions of label approval</b>	<b>41</b>
Changes to labels	41
Label variations	50
<b>4.2 Affirm product registration and label approval</b>	<b>51</b>
<b>4.3 Cancellation of all but the most recently approved label</b>	<b>51</b>
<b>4.4 Cancellation as a consequence of review findings</b>	<b>52</b>
<b>4.5 Withdrawn carbaryl products</b>	<b>52</b>
<hr/>	
<b>5 AMENDMENTS TO STANDARDS</b>	<b>54</b>
<b>5.1 Public health standards</b>	<b>54</b>
Acceptable Daily Intake	54
Acute Reference Dose	54
Health value for Australian drinking water	54
Poisons schedule	54
First Aid Instructions	54
Safety Directions and personal protective equipment	55
Warning statements	57
<b>5.2 Maximum Residue Limits Standard</b>	<b>57</b>
<hr/>	
<b>APPENDIX</b>	<b>62</b>

## OVERVIEW

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has completed its review of the carbaryl products used in agricultural situations and their associated approved labels.

Carbaryl is a broad spectrum, general purpose carbamate insecticide with a very short persistence. It is effective against a range of insects and other arthropod pests including mites, lice and millipedes. It is used in a diverse range of situations encompassing a wide range of agricultural crops, and industrial and commercial uses.

The APVMA has affirmed the approvals of the active constituent carbaryl. The registrations of products containing carbaryl (except a wettable powder (WP) product) have been affirmed following amendment of labels by deleting some uses, amending directions for some uses, and strengthening warning statements and safety directions.

Products containing carbaryl as a WP will not be affirmed due to occupational health and safety (OHS) risks unless they are contained in measured water-soluble packaging (WSP). To date this change has not occurred and the single WP product has been voluntarily cancelled.

This final decision has taken into account the public comments and residues data received in response to the 2006 Preliminary Review Findings (PRF) report.

Additionally, dietary exposure calculations have been updated to reflect the most recent survey of Australian dietary intake. Following consultation with representatives from affected user groups the APVMA decided that the 3-day withholding period (WHP) for raspberries was not acceptable (a 7-day WHP is acceptable) and that the use of carbaryl on stored cereal grain was not acceptable. There is no change to the use patterns for cereal grains before harvest, nor to the use of carbaryl to disinfest grain storage structures when grain is not present.

## EXECUTIVE SUMMARY

### Introduction

The APVMA has completed the assessment of data and information relating to registered carbaryl products used in agricultural situations and their associated label approvals. This Final Review Report and Regulatory Decision document covers the review of carbaryl products used in agricultural situations. The report provides details of the assessment of data and information for carbaryl products used in agricultural situations and details the regulatory action that has been taken in relation to these products.

The review of carbaryl products used in the home garden, home veterinary, poultry and domestic situations was completed separately in January 2007 with the cancellation of several products and changes to label instructions. Further information on home garden and domestic uses is available from: [www.apvma.gov.au/products/review/current/carbaryl.php](http://www.apvma.gov.au/products/review/current/carbaryl.php).

Carbaryl is a carbamate insecticide used for controlling insect pests in home garden and domestic situations, on ornamental plants, fruit and vegetables, and around buildings. Major agricultural uses of carbaryl include tree and vine crops (avocados, citrus, grapes), fruit and vegetable crops (beans, carrots, strawberries), field crops and stored grain (cotton, lucerne, pasture), in ornamental plants and around agricultural buildings. Carbaryl is effective in controlling many arthropod pests including millipedes, beetles, ants, weevils and caterpillars.

Formulations of carbaryl include emulsifiable concentrates, suspension concentrates (SCs), wettable powders (WPs) and solid formulations. Six registered carbaryl products used in agricultural situations were considered as part of this review and their formulation types are SCs (three products), WP (one product) and solid (two products) (see Appendix).

### Review findings

#### Toxicological assessment

The toxicological assessment for the review of carbaryl was undertaken by the Office of Chemical Safety (OCS), which considered all the toxicological data and information submitted for the review.

The OCS considered the health intake standards for carbaryl. The Acceptable Daily Intake (ADI) was amended from 0.004 mg/kg bw/d to 0.008 mg/kg bw/d and an Acute Reference Dose (ARfD) was established at 0.01 mg/kg bw. These standards were used in the assessment of dietary exposure from residues. The toxicological assessment also formed the basis of the occupational health and safety risk assessment.

The APVMA considered the advice received from the OCS and concluded that product labels should be varied to include new warning statements and safety directions.

## Occupational health and safety assessment

The occupational health and safety assessment for the review of carbaryl was undertaken by the OCS, which considered all the occupational health and safety data and information submitted for the review. The APVMA considered the advice received from the OCS and made the following findings for the continued use of products containing carbaryl used in agricultural situations.

The APVMA was not satisfied that the mixing and loading of carbaryl 800 g/kg WP products would not be an undue hazard to the safety of people and would not have an effect that is harmful to human beings. The APVMA can be satisfied that if the delivery method for carbaryl as an 800 g/kg WP formulation were to be changed to be provided in Water-Soluble Packaging (WSP) it would not be an undue hazard to the safety of people exposed to it during its mixing and loading and that it would not have an effect that is harmful to human beings. The APVMA could be satisfied that the use of the carbaryl 800 g/kg WP formulation provided in WSP applied by hand-held application to garden beds and compost heaps, and treatment around buildings would not be an undue hazard to the safety of people exposed to it during its handling, and that it would not have an effect that is harmful to human beings. Therefore, the 800 g/kg WP carbaryl products will be only be acceptable if packaged in WSP.

The APVMA was not satisfied that the continued use of carbaryl by high-volume powered hand-held spray equipment (other than knapsack equipment) for pest control activities in domestic, commercial and industrial settings, except for the eradication of insect nests, would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings. The APVMA has deleted uses requiring this application method from the label (except for the eradication of insect nests).

The APVMA was satisfied that mixing, loading and application of carbaryl SC formulations by orchard airblast and boomspray would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings.

The APVMA was not satisfied that mixing and loading by operators of carbaryl SC products for aerial application would not be an undue hazard. However, the APVMA can be satisfied that mixing and loading by operators of carbaryl SC products for aerial application via an enclosed transfer/mixing system would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings. Therefore, labels have been varied to require enclosed transfer/mixing systems for preparation of carbaryl SC products for aerial spraying.

The APVMA is satisfied that continued application of carbaryl SC products by ground boom spray and hand-held spray equipment to trees, ornamental plants, pigs and grain storage infrastructure would not be an undue hazard to the safety of people exposed to it during its handling and that it would not have an effect that is harmful to human beings.

## Residues assessment

The residues assessment for the review of carbaryl was undertaken by the APVMA Residues Team, which considered all the residue data and information submitted for the review. The APVMA makes the following findings relating to the continued use of products containing carbaryl used in agricultural situations.

The APVMA was not satisfied that the continued use of carbaryl for use on cereal grains for post-harvest storage, berry fruits (except raspberries and strawberry runners), carrots, citrus (except oranges and lemons), cherries, kiwifruit, fruit general, grapes (except butt treatment), sunflower, sweetcorn, linseed crops and vegetable crops (except potatoes, sweet potato, beetroot and turnip (swede), and pre-flowering uses on cucurbits), would not be an undue hazard to the safety of people using anything containing its residues. Therefore, instructions for use for the above crops have been deleted from labels.

The APVMA was not satisfied that the continued use of carbaryl for cucurbits, feijoas, guavas, grapes, jaboticaba, jackfruit, litchis (alternately spelled lychees, the codex spelling: 'litchis' is used throughout this report) and rambutans would not be an undue hazard to the safety of people using anything containing its residues. However, the APVMA could be satisfied that uses of carbaryl on non-flowering/non-fruiting trees/plants for the above listed crops would not be an undue hazard to the safety of people using anything containing its residues. Therefore, the product labels have been varied to limit the use of carbaryl on these plants.

The APVMA was satisfied that continued use of registered carbaryl products on avocados, cotton, mangoes, macadamias, pecans, pome fruit (apples, pears and loquats (Japanese medlar)), stone fruit (except cherries), citrus (oranges and lemons only), potatoes and sweet potato, raspberries, beetroot and turnips (swede) would not be an undue hazard to the safety of people using anything containing its residues. Therefore, these use patterns remain.

The APVMA was satisfied that continued use of registered carbaryl products as a pre-harvest treatment on cereal crops, empty grain storage structures, lucerne, maize, pastures, pasture seed crops, rice and sorghum would not be an undue hazard to the safety of people using anything containing its residues. Therefore, these use patterns remain.

One carbaryl product was registered for use as a direct treatment for pigs. The APVMA was satisfied that the use of this product in accordance with the instructions for its use would not result in residues in pork commodities exceeding the limits established. Therefore, the APVMA was satisfied that the use of the product would not be an undue hazard to the safety of people using anything containing its residues. However, the registration of this product was not renewed by the registrant and, at the time of finalisation of this review, there were no products registered for use on pigs.

Livestock may be exposed to residues of carbaryl. Sufficient data were available to assess residues in animal commodities resulting from dietary exposure to feeds containing carbaryl residues. The APVMA was satisfied that the use of carbaryl products on potential animal feeds (except cotton) in accordance with the

instructions for use would not be an undue hazard to the safety of people using anything containing its residues. Therefore, these use patterns remain.

Carbaryl products are also registered for use in various situations considered to be non-food uses (that is, not for human or livestock consumption) as a pesticide in commercial, industrial and domestic areas, tobacco storage sheds and rights of way, in non-crop areas in general, on ornamentals, roses, elm trees (in non-crop situations), kenaf, duboisia and rosella. There were no residues issues relating to non-food uses of carbaryl products. Therefore the APVMA was satisfied that the use of carbaryl products in the above non-crop areas in accordance with the instructions for use would not be an undue hazard to the safety of people using anything containing its residues. Therefore, these use patterns remain.

## Public submissions

Following the July 2006 publication of *Part 2 Uses of carbaryl in agricultural situations Preliminary Review Findings* the APVMA received submissions to the review in relation to the toxicology and OHS assessments from:

- the Queensland Department of Agriculture, Fisheries and Forestry
- the NSW Environment Protection Authority
- the Australian Mango Industry Association Limited
- Avocados Australia Limited
- Horticulture Australia Limited
- Kendon Plant Care.

The submissions were in regard to re-entry periods, terminology, the toxicological assessment, application methods, the WP formulation and Withholding periods (WHPs). Further details of the submissions and the responses can be found in Section 3.5 of this report.

As a result of the public submissions, additional residues data and the National Estimated Daily Intake (NEDI) and National Estimated Short-Term Intake (NESTI) calculations based on Food Standards Australia New Zealand's 2009 revision of consumption figures (rather than the 1995 consumption data used in the previous report), APVMA and its expert agencies have reconsidered certain aspects of the assessments for human health and residues. Resulting from this reassessment the following changes have been made to the final outcomes that differ from those listed in the previously published PRF report:

- Use on storage grains and cereals (post-harvest) has been deleted (but the treatment of empty grain storage structures is to remain on the label).
- The WHP for raspberries has been increased from 3 days to 7 days.

- Use on strawberries has not been deleted; however, use has been limited to commercial runner production (that is, non-fruiting plants) only.
- Based on the submission of additional residue data, a WHP of 3 days has been set for avocados and 7 days for mangoes. Therefore, uses are not restricted to non-flowering plants as previously recommended.
- Uses on oranges and lemons have been retained following a reduction in maximum use rates on the label.
- Use on sweet potato has been retained, based on its similarity to potato and residues data of potato.
- It is noted that there are no sugarbeet uses on labels and no indication that there is any use of carbaryl on sugarbeet.
- The use of WP formulations by hand-held application to garden beds, compost heaps and treatment around buildings can be retained if the WP formulations are to be supplied in measured WSP.
- Operators applying carbaryl by orchard airblast are not required to be protected by engineering controls.
- The use of enclosed transfer/mixing systems for preparation of carbaryl SC products is not required for boomspray and orchard airblast application.
- Re-entry periods for tree crops and all other crops have been amended to 1 day based on the likely exposure of workers.

## Final review outcomes

After consideration of all data including the additional assessments, the APVMA has taken the following regulatory actions:

### (a) Vary label approvals

- The following instructions for use have been deleted from product labels: post-harvest use on stored cereal grains, berry fruits (except raspberries and strawberry commercial runners), fruit general, citrus (except oranges and lemons), cherries, kiwifruit, grapes (except butt treatment), sunflower and linseed crops, and vegetable crops.
- The general vegetable crops use has been replaced by the specific crops (beetroot and turnip (swede)), and limited uses on cucurbits/melons.
- The uses on the following crops have been limited to non-flowering and non-fruiting trees and plants: feijoas, guavas, jaboticaba, jackfruit, litchis, rambutans, cucurbits/melons (before flowering).
- Use on grapes with a longer WHP was not considered to be acceptable but the use to control cutworms by treatment of the base of vines only has been retained.

- Use on strawberries has been limited to commercial runner production (that is, non-fruiting plants) only.
- The uses for macadamias, pecans, pome fruit (apples, loquats and pears), stone fruit (except cherries), citrus (oranges and lemons), potatoes and sweet potato, raspberries, beetroot, turnips (swede), cereal crops (pre-harvest), cotton, duboisia and kenaf (non-food use), lucerne, maize, pastures, pasture seed crops, rice, rosella, sorghum, elm trees, ornamentals and roses have been retained with some changes to WHPs.
- The uses in commercial, industrial and domestic areas, in tobacco storage sheds, in rights of way, in non-crop areas in general, and for treatment on horses, ponies and dogs have been retained.
- The delivery method for WP formulations must be changed to be provided in measure packs in WSP. (The single registered WP product not packaged in WSP has been cancelled.)
- The application of products by high-volume powered hand-held spray equipment for pest control activities in domestic, commercial and industrial settings has been deleted from labels (except for the eradication of insect nests).
- The use of enclosed transfer/mixing systems for preparation of carbaryl SC products is required for aerial application to reduce the exposure of operators mixing and loading to acceptable levels.
- WHPs have been amended and updated on product labels.
- Re-entry periods have been established and placed on product labels.
- First Aid Instructions, Warning Statements and Safety Directions have been updated on product labels.
- Old approved labels that were deemed not to contain adequate instructions have been cancelled.

**(b) Affirm product registrations**

- The variations to product labels have been made and therefore satisfy the requirements for continued registration. As a result the product registrations of four products (listed in Table 15) have been affirmed.

**(c) Cancel product registration**

- The registration of the WP product was voluntarily cancelled by the registrant on 10 January 2012.

## 1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has considered the registration of products containing carbaryl intended for use in agricultural situations and all associated label approvals. The purpose of this document is to provide a summary of the data evaluated and the regulatory decisions.

### 1.1 Regulatory status of carbaryl in Australia

Carbaryl has been registered in Australia for over 30 years. There were six registered products for use in agricultural situations (Appendix) in July 2006 at the time of publication of *Part 2 Uses of carbaryl in agricultural situations Preliminary Review Findings*. (As at the time of publication of this final review report only four of these products are still registered). Formulations of carbaryl include suspension concentrates (SCs), a wettable powder (WP), a lotion and a solid formulation. The formulation types are set out in Table 1. Information on the uses of carbaryl products can be found in Chapter 2 of this report.

**Table 1: Registered formulations of carbaryl under consideration in the review**

FORMULATION TYPE	LEVEL OF ACTIVE CONSTITUENT	PACK SIZES	PRODUCT TYPE
Suspension concentrates (SC)	500 g/L	1 L, 2.5 L, 5 L, 10 L, 20 L	Agricultural insecticide
Wettable powders (WP)	800 g/kg	1 kg, 10 kg, 25 kg	Agricultural insecticide
Lotion	2 g/L	500 ml	Horse and dog ectoparasiticide shampoo
Bar	37.2 g/kg	350 g	Dry insecticidal shampoo for horses and ponies

### 1.2 Reasons for the carbaryl review

In 1993 the maximum residue limits (MRLs) for carbaryl use on cereal crops were withdrawn following a residue assessment which showed that the available Australian residue data were inadequate to support the existing MRLs. Temporary MRLs were put in place at that time to allow trials to be performed.

Residue data were subsequently provided to support ratification of the temporary MRLs in relation to the use of carbaryl in cereals, either by field application or for stored grain use. A review was initiated in 1995 to reconsider residues in cereals and also to establish MRLs for animals that may be fed on treated cereal products.

In 1999, toxicology reviewers also identified the potential for excessive human exposure to carbaryl. This was considered to have implications for the exposure of consumers through use of carbaryl in the home garden. Therefore, the scope of the review was extended to reconsider whether the uses of carbaryl

products for home garden and home veterinary applications (and their associated labels) would have an effect that was harmful to human beings.

In June 2003 the APVMA extended the scope of the review a second time when concerns about the implications of acute dietary intake of carbaryl were identified. This was in response to the setting of an Acute Reference Dose (ARfD) by the Office of Chemical Safety (OCS).

In June 2004, the APVMA released the carbaryl Draft Final Report for public consultation. The Draft Report provided a summary of the data evaluated and the proposed regulatory decisions, as a result of the review of carbaryl. In response to the release of the report, comments were received by a number of industries and state authorities. These comments were considered and resulted in a number of changes to the recommendations that appeared in the Draft Report.

At the time that the Draft Report was released, it was also identified that an occupational health and safety assessment needed to be undertaken for carbaryl products used in commercial agricultural situations. As further assessments were required, it was decided that the review would be split into two parts to enable the review of home garden, home veterinary, poultry and domestic products to be finalised. In January 2007 the APVMA released the Final Review Report and Regulatory Decision for the review of carbaryl Part 1, which dealt with home garden, home veterinary, poultry and domestic products.

In July 2006 the APVMA released the Preliminary Review Findings (PRF) report Part 2 for products used in agricultural situations for public comment. This PRF report recommended a number of changes to application methods and the deletion of some uses. A number of comments were received on the recommendations in this 2006 PRF report and the avocado and mango industries submitted additional residues data to establish more appropriate WHPs for the use of carbaryl in these crops. These comments and data have been assessed and the review of carbaryl products used in agricultural situations has now been finalised.

### 1.3 Scope of the review

When the extent of the review was scoped, the reasons for the nomination of carbaryl, the information already available on this chemical and the approved uses of the product in Australia were taken into account.

In light of concerns raised by the OCS and the APVMA, it did not appear that the APVMA could be satisfied that the continued use of, or any other dealing with, products containing carbaryl in accordance with the approved instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, and/or
- would not be likely to have an effect that is harmful to human beings.

The APVMA also considered whether product labels carried adequate instructions and warning statements. Such instructions should include:

- the circumstances in which the product should be used
- how the product should be used
- the times when the product should be used
- the frequency of the use of the product
- the withholding period (WHP) after the use of the product
- the disposal of the product and its container
- the safe handling of the product.

On the basis of the human health and residues concerns, it was decided that product registrations and label approvals for carbaryl should be reviewed under the provisions of Part 2, Division 4, of the Agvet Codes.

The APVMA reviewed the following aspects of product registrations and label approvals for carbaryl:

- toxicology, including:
  - the potential for home garden, home veterinary and domestic products to have harmful effects on human beings (considered in Part 1, which was finalised in January 2007)
  - the potential for commercial agricultural uses to have harmful effects on human beings (considered in this review, Part 2)
- occupational health and safety, including:
  - the potential for unacceptable exposure to agricultural products
- residues in food, including:
  - the potential for occurrence of carbaryl residues in treated produce
  - the potential for acute and chronic dietary exposure to carbaryl residues in food commodities
  - the potential for carbaryl residues in food to prejudice trade or commerce between Australia and places outside Australia.

## 1.4 Regulatory options

There can be three possible outcomes to the reconsideration of the registration of products containing carbaryl and their labels. Based on the information reviewed the APVMA may be:

- satisfied that the products and their labels continue to meet the prescribed requirements for registration and approval and therefore affirms the registrations and approvals
- satisfied that the conditions to which the registration or approval can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval
- not satisfied that the requirements for continued registration and approval continue to be met and thus suspends or cancels the registration and/or approval.

## 2 APPROVED CARBARYL USE PATTERNS

### 2.1 Agricultural uses of carbaryl in Australia at the time of the review

Carbaryl, a broad spectrum, general purpose carbamate pesticide with a very short persistence, is effective against a range of insects including mites, lice, millipedes and other pests. It was used in a diverse range of situations encompassing a wide range of agricultural crops, and industrial and commercial uses.

#### Tree and vine crops

Carbaryl products were used to control a wide range of insect pests on a variety of tropical and non-tropical tree and vine crops (Table 2).

**Table 2: Uses of carbaryl in tree and vine crops considered in this review**

CROP	PESTS	PRODUCT DESCRIPTION	APPLICATION INSTRUCTIONS	COMMENTS
Avocado	Red-shouldered leaf beetle	500 g/L	200 ml/100 L	Apply when infestation is first observed and repeat as swarms re-infest.
	Monolepta beetle (NSW + QLD)	800 g/kg	130 g/100 L	
Citrus	Bronze orange bug, citrus leaf-eating caterpillar, Fuller's rose weevil, fruit-piercing moth, light brown apple moth, orange fruit borer, pink wax scale, spined citrus bug, white wax scale, yellow peach moth	500 g/L	160–200 ml/100 L	Apply at first sign of pest activity and repeat at intervals of 2 weeks or as necessary. Use higher rate when higher insect pressure occurs.
		800 g/kg	100–130 g/100 L	
Feijoa, guava	Orange fruit borer	500 g/L	200 ml/100 L	Spray trees thoroughly to dripping point in late November to early December followed by a second application in late January to early February. Add summer oil.
Fruit—general	Wingless grasshopper	500 g/L	175 ml/100 L	Spray infested area thoroughly as required.
Grape	Grapeleaf blister mite, grapevine hawk moth, grapevine moth, light brown apple moth, cutworms, mealybugs, scale	500 g/L	160–200 ml/100 L	Apply at first sign of pest activity and repeat at intervals of 2 weeks or as necessary. Use higher rate when higher insect pressure occurs.
		800 g/kg	100–130 g/100 L	

CROP	PESTS	PRODUCT DESCRIPTION	APPLICATION INSTRUCTIONS	COMMENTS
Jaboticaba, Jackfruit	Swarming leaf beetle	500 g/L	200 ml/100 L	Several applications may be needed. Do not apply during flowering.
Kiwifruit	Light brown apple moth	500 g/L	160–200 ml/100 L	Apply when pests appear and repeat as necessary. Apply as high-volume spray at 7–10 day intervals when pests present. Use higher rate where high insect pressure occurs.
Loquat	Light brown apple moth	500 g/L	200 ml/100 L	Apply at first sign of pests and repeat as necessary.
Litchi	Caster oil looper, leaf-eating looper, macadamia nutborer, red-shouldered leaf beetle, swarming leaf beetle	500 g/L	200 ml/100 L	Apply at first sign of pests and repeat as necessary.
Macadamia	Macadamia nutborer, macadamia twig-girdler, red-shouldered leaf beetle, cornelian (butterfly), macadamia cup moth, macadamia nut moth, yellow peach moth	500 g/L	200 ml/100 L or 2.2 L/ha	Apply a preventative spray after moths have been flying.
		800 g/kg	130 g/100 L	Four sprays at 2–3 week intervals during late Nov. to Feb.
Mango	Fig leafhoppers, pink wax scale, flatids	500 g/L	200 ml/100 L	Apply when populations appear on leaf stalks (Oct–Nov).
		800 g/kg	90 g/100 L	
Pecan	Orange fruitborer, yellow peach moth	500 g/L	200 ml/100 L	Apply to mature trees carrying nuts. Direct spray to clusters of nuts where pests build up.
Pome fruit: Apples, pears	Early fruit caterpillars, codling moth, light brown apple moth, pear leaf blister mite, pear and cherry slug	500 g/L	160–200 ml/100 L	Apply at 1st sign of pest activity. Repeat spray at 21-day intervals during the season. Use higher rate where high insect pressure occurs.
		800 g/kg	130 g/100 L	
	Fruit thinning	500 g/L	160–200 ml/100 L	
		800 g/kg	100–130 g/100 L	Apply to apples and pears between 7 and 28 days following full bloom. Should other factors be likely to cause thinning apply this product with caution. If no reduction in fruit set is desired do not apply within 30 days of full bloom.

CROP	PESTS	PRODUCT DESCRIPTION	APPLICATION INSTRUCTIONS	COMMENTS
Rambutan	Caster oil looper, red-shouldered leaf beetle, swarming leaf beetle	500 g/L	200 ml/100 L	Apply at 1st sign of pests and repeat as required.
Stone fruit: Apricots, nectarines, peaches, plums, prunes	Green treehopper, light brown apple moth, oriental fruit moth, pear and cherry slug, red-shouldered leaf beetle, orange fruit borer, <i>Heliothis</i> (budworms), European earwig	500 g/L 800 g/kg	160–200 ml/100 L 100–180 g/100 L	Apply at first sign of pest activity and repeat at intervals of 2 weeks or as necessary. Use higher rate when higher insect pressure occurs.

## Fruit and vegetable crops

Carbaryl products are used for the control of a large number of insect pests in a wide variety of fruit and vegetable crops (Table 3). The application of carbaryl on crops is dependent on a number of variables, including crop type and pest pressure. Types of application can be either dilute high-volume spraying or concentrated low-volume spraying.

**Table 3: Uses of carbaryl in fruit and vegetable crops considered in this review**

CROP	PEST	PRODUCT DESCRIPTION	MAXIMUM RATE	COMMENTS
Beans	<i>Heliothis</i> (budworms), pumpkin beetle, 28-spotted ladybird	500 g/L	200 ml/100 L	Apply at first sign of pest activity and repeat at as necessary.
		800 g/kg	130 g/100 L	
Blueberries	Grasshoppers	500 g/L	200 ml/100 L	Apply at first sign of pest activity and repeat at 2-week intervals or as necessary.
Cape gooseberry	Threelined potato beetle	500 g/L	200 ml/100 L	Apply at first sign of pest activity and repeat at 2 week intervals or as necessary.
Capsicum	Beetles, weevils	500 g/L	200 ml/100 L	Apply at first sign of pest activity and repeat at as necessary.
Carrot	Vegetable weevil	500 g/L	200 ml/100 L	Apply at first sign of pest activity and repeat at as necessary.
		800 g/kg	130 g/100 L	
Cucurbit	Cucurbit stemborer, <i>Heliothis</i> (budworms), pumpkin beetle, 28-spotted ladybird	500 g/L	200 ml/100 L	Apply at first sign of pest activity and repeat at as necessary.
		800 g/kg	130 g/100 L	

CROP	PEST	PRODUCT DESCRIPTION	MAXIMUM RATE	COMMENTS
Leafy and root vegetables	Vegetable weevil, brown vegetable weevil	500 g/L	300 ml/100 L	Apply at first sign of pest activity and repeat at as necessary.
		800 g/kg	190 g/100 L	
Potato	Potato moth	500 g/L	200 ml/100 L or 2.2 L/ha	Apply at 1st sign of moth activity. Use sufficient water for good coverage. One or two sprays at 3–4 weeks intervals could be required.
		800 g/kg	1.4 kg/ha	
Raspberries	Grasshoppers, light brown apple moth, raspberry fruit caterpillar	500 g/L	200 ml/100 L	Apply at 1st sign of pests and repeat as required.
Strawberry	Grasshoppers	500 g/L	200 ml/100 L	Apply at 1st sign of pests and repeat as required.
Tomato	Leafminer caterpillars, tomato leaf miner, false wireworm	500 g/L	200 ml/100 L or 2.2 L/ha	Spray plants thoroughly to the point of wetness at the first sign of attack.
		800 g/kg	130 g/100 L	
Vegetables—general	Potato moth, European earwig, cabbage white butterfly, cabbage moth, Rutherglen bug, pumpkin beetle, 28-spotted (leaf eating) ladybird, cutworms, green vegetable weevil, vegetable bug; wingless grasshoppers	800 g/kg	100–190 g/100 L 320 ml/100 L	Apply when pest appears and repeat as necessary. Use higher rates where high insect pressure occurs.

### Field crops, pastures and stored grain

Carbaryl is registered for use on field crops and pastures and is applied during the growing stages for control of certain insect pests (Table 4). It is also registered for use as a grain protectant chemical during grain storage and for treatment of structures where grain is stored.

Table 4: Uses of carbaryl in field crops, pastures and stored grain considered in this review

CROP	PEST	PRODUCT DESCRIPTION	MAXIMUM RATE	COMMENTS
Cereal grain storage up to 3 months (except malting barley)	Lesser grain borer	500 g/L	10 ml/L water per tonne of grain	Applied through conventional grain spraying equipment.
Cereal, grain storage from 3 months up to 9 months			16 ml/L per tonne grain	Applied through conventional grain spraying equipment.
Grain stores (surface spraying)				
Disinfection of grain storage buildings			10 ml/L water per 10 square meters	Applied to surfaces of storage areas—spray to runoff.
Cereals (general)	Rutherglen Bug, <i>Heliothis</i> spp, armyworms, cutworms, Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	500 g/L or 800 g/kg	80–100 g ac/100 L or 900–1100 g ac/ha  160–200 ml/100 L water	Apply at first sign of pest activity and repeat as necessary. For aerial application: apply in not less than 15–20 L water. (Do not apply by air in NSW.)
Cotton	Rough bollworm	500 g/L	200 ml/100 L or 2.2 L/ha	Apply when pest appears and repeat at 7–14 day intervals as necessary. DO NOT use on cotton after 25% of bolls have opened.
Duboisia	Australian plague locust, cluster caterpillar, grasshoppers, leaf-eating ladybirds, sandal-box hawk moth	500 g/L  800 g/kg	200 ml/100 L or 2.2 L/ha  130 g/100 L	Apply when pest appears and repeat as necessary.
Kenaf	Red-shouldered leaf beetle	500 g/L	2.2 L/ha	Apply as pest pressure indicates.
Linseed	<i>Heliothis</i> (budworms)	500 g/L	200 ml/100 L or 2.2 L/ha	Apply when pest appears and repeat as necessary.
Lucerne	<i>Heliothis</i> (budworms), leafhoppers (jassids)	500 g/L	500ml – 2.2 L/ha	Apply at 1st sign of pest activity and repeat as necessary. Use sufficient water for adequate coverage.
	Leaf roller, lucerne flea, sitona weevil	800 g/kg	1.0–1.4 kg/ha	

CROP	PEST	PRODUCT DESCRIPTION	MAXIMUM RATE	COMMENTS
Maize	Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	500 g/kg	1.2–1.4 L/ha	Apply when pests first appear and repeat as necessary. Use higher rates on adults.
Pastures, pasture seed crops	Lucerne leafroller, grass caterpillar, pasture cockchafer, armyworms, <i>Heliothis</i> (budworms), pasture leafhopper, sitona weevil, cutworms	500 g/L	1.8–2.2 L/ha	Apply when pests first appear and repeat as necessary. Use higher rates on adults.
	Yellow-winged locust, migratory locust, Australian plague locust	800 g/kg	1.2–1.4 L/ha	
Rice	Brown planthopper	500 g/L	2.2 L/ha	Apply as pest populations indicate. Under heavy pressure, re-treatment after 14 days may be necessary.
Rosella	Leaf-eating beetles	500 g/L	200 ml/100 L	Apply at first sign of pest activity and repeat as necessary.
Sorghum	Sorghum midge, Rutherglen bug, <i>Heliothis</i> spp, armyworms, cutworms	500 g/L	1.8–2.2 L/ha	First application when 1–2 midges per head present and when 90% heads emerged. Further application at 4-day intervals may be required depending on crop potential.
	Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	500 g/L	1.2–1.4 L/ha	Apply when pests first appear and repeat as necessary. Use higher rates on adults.
Sunflower	Black sunflower scarab, sorghum midge, Rutherglen bug, <i>Heliothis</i> spp, armyworms, cutworms, wingless grasshopper	500 g/L	1 L/ha	Apply to newly emerged plants when pest pressure and repeat as necessary.
Sweet corn	Red-shouldered leaf beetle	500 g/L	1.6–2.0 L/ha	Apply at first sign of pest activity and repeat as necessary.

## Ornamentals

Carbaryl is registered for use on ornamentals, elm trees and roses and is applied during the growing stages for control of a range of insect pests (Table 5).

**Table 5: Uses of carbaryl in ornamentals considered in this review**

SITUATION	PEST	PRODUCT DESCRIPTION	MAXIMUM RATE	COMMENTS
Elm trees	Elm leaf beetle	500 g/L	200 ml/L	Apply to trunk of tree in spring when larvae are first observed on leaves. A repeat spray should be applied 4–6 weeks later if large numbers of larvae are found on leaves.
		800 g/kg	2.5 kg/100 L	
		800 g/kg	125 g/100 L	If large numbers of larvae threaten to defoliate small specimen trees, a carbaryl spray may be applied to the foliage. Repeat spray when required.
Ornamentals	Tobacco leaf miner, potato moth, earwig, cabbage moth, cabbage white butterfly, Rutherglen bug, green vegetable bug, leaf-eating ladybird, <i>Heliothis</i> spp, pumpkin beetle, cutworms, wingless grasshopper, beetles, caterpillars, chewing insects, sucking insects, leafroller moth, looper, white wax scale	500 g/L	160–200 ml/L or 1.8–2.2 L/ha	Apply when pests appear. Repeat as necessary.
Roses	Cluster caterpillar, light brown apple moth	500 g/L	200 ml/100 L	Apply at first sign of pest activity and then as necessary. Spray to point of wetness.

## Miscellaneous uses

Products containing carbaryl are used in a number of miscellaneous situations (Table 6). These uses include controlling insect pests around outbuildings or sheds and in right-of-way areas. Application in these areas is dependent on the pest and is mostly applied as a spray from an agricultural spray unit, high-volume powered hand-held spray, knapsack or hand-held spray pack and by direct application of liquid from a squirt bottle.

Table 6: Miscellaneous uses of carbaryl considered in this review

SITUATION	PEST	PRODUCT DESCRIPTION	MAXIMUM RATE	COMMENTS
Concealed or underground nests in and around home garden, shed	Vespid wasp (English/European wasps), honey bees in concealed hives	500 g/L	1.1L/100 L	Spray into nests in the open and in enclosed cavities where the nest is close to the entrance used by bees.
Garden beds, compost heaps, treatment around buildings	Black Portuguese millipede	800 g/kg	50 g/5 L of water to cover an area 30 square metres	Hand application. Spray source of infestation. Spray paths around buildings and walls to a height of 1 metre to form a protective barrier.
Tobacco bulk sheds	Tobacco beetles, ants, fleas, moths, weevils, European earwig	500 g/L	200 ml/10 L	Spray all surfaces. Apply 5 L of prepared spray to 100 square metres.
Commercial and industrial areas	Ants, fleas, moths, weevils		2.2 L/100 L	Spray thoroughly all surfaces to be treated.
	Vespid wasp (English/European wasps)	500 g/L	130–320 ml/L	Pour or squirt down the entrance to underground nests or spray semi-concealed nests.
	Honey bees	500 g/L	1.1 L/100 L	Spray into nests in the open and enclosed cavities where nest is close to the entrance used by the bees. Destroy nest if accessible.
	European earwig	500 g/L	80 ml/15 L	Spray on exterior walls of houses and outbuildings, boundary fences and breeding places such as wood piles and reserves.
Non-crop, commercial and industrial areas, rights of way	Plague grasshopper, plague locust	500 g/L	1.1-1.4 L/100 L	For treatment of swarms by high-volume ground equipment. Use sufficient volume of water to get a good coverage, usually between 220 and 1100 L/ ha.
	Wingless grasshopper	500 g/L	160 ml/100 L	
	European earwig	500 g/L	80 ml/15 L	Knapsack application.
		500 g/L	55 ml/10 L	Spray on exterior walls of houses and outbuildings, boundary fences and breeding places such as wood piles and reserves. Repeat after 4 weeks.

## Animal treatment

Two products containing carbaryl were registered for the control of ectoparasites on horses and dogs. One carbaryl product was also registered for the control of body louse and sarcoptic mange on pigs. This product was considered in the review but is no longer registered (Table 7).

**Table 7: Animal treatment using carbaryl products considered in this review**

ANIMAL	PEST	PRODUCT DESCRIPTION	COMMENTS
Horses and ponies	Sucking louse, body louse, hard ticks, bush tick, mites, ear mites, leg mange	Dry soap bar: 37.2 g/kg carbaryl	Smoothly draw block against coat of the animal, both with and against the lay of the coat. Apply freely once a day. Repeat as necessary.
Horses and dogs	Mange, girth itch, Queensland itch, lice	Animal insecticide bactericide lotion: 2 g/L carbaryl 50 g/L zinc oxide 20 g/L sulfur	Shampoo coat and rinse thoroughly. If possible clip hair around affected parts.
Pigs	Body louse, sarcoptic mange	Suspension concentrates: 500 g/L carbaryl (application rate 50–100 ml/10 L)	Spray pigs thoroughly to wetness. Repeat application 10–14 days later

## 3 SUMMARY OF DATA ASSESSMENTS

### 3.1 Toxicology

The toxicological assessment for the review of carbaryl was undertaken by the OCS. The OCS considered all the toxicological data and information submitted for the review. The toxicological findings are summarised below.

#### Introduction

The toxicological assessment examined:

1. studies intended to elucidate the mechanism of tumour formation by carbaryl dosing
2. multi-generation and reproduction and developmental studies in rats and rabbits
3. addenda to a previously evaluated developmental neurotoxicity study in rats
4. a short-term repeat-dose study and a 1-year study in dogs
5. exposure studies undertaken on persons using American registered carbaryl products in simulated domestic settings.

The systemic doses likely to be delivered to users of registered carbaryl products under Australian conditions have also been estimated. These estimates have been related to toxicological benchmarks and recommendations made on the continued registration and conditions of use of carbaryl products. The Acceptable Daily Intake (ADI) of 0.008 mg/kg bw/d was based on vascular tumour formation, and the ARfD of 0.01 mg/kg bodyweight (bw) was based on cholinesterase (ChE) inhibition, clinical signs, and reduced bw gain.

## Toxicology hazard profile

### Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption	Oral absorption is rapid and extensive in humans, rodents and other species.  Dermal absorption from aqueous media is slow and saturable in rodents but enhanced in the presence of organic solvents.  Pulmonary absorption is rapid.
Distribution	Small amounts in carcass, kidney and liver.
Potential for accumulation	Very low.
Rate and extent of excretion	Rapid, extensive, predominantly via urine in all species except dog.
Metabolism	Rapid. Proceeds via hydrolysis, alkyl oxidation, arene oxide formation, epoxide hydrolysis and glutathione conjugation. Pathways similar in humans, rodents and other species investigated.
Toxicologically significant compounds (animals, plants and environment)	Reactive epoxide intermediates may be formed in mice and rats.

### ACUTE TOXICITY

Rat oral LD <sub>50</sub> (mg/kg bw)	246
Worst oral LD <sub>50</sub> in other species	150 mg/kg bw in cats
Rat dermal LD <sub>50</sub> (mg/kg bw)	No data
Worst dermal LD <sub>50</sub> in other species	> 2000 mg/kg bw in rabbits
Rat inhalation LC <sub>50</sub> (mg/m <sup>3</sup> )	2500 (4 hours) as aerosol
Worst inhalation LC <sub>50</sub> in other species	No data
Skin irritation	Classified as slight in rabbits
Eye irritation	Classified as not irritating in rabbits
Skin sensitisation	None in guinea pigs

### METABOLITES OF CARBARYL

Rat oral LD <sub>50</sub> (mg/kg bw)	
4-hydroxycarbaryl	1190
5-hydroxycarbaryl	297
7-hydroxycarbaryl	4760

Hydroxymethylcarbaryl	> 5000
1-naphthol	2570
<b>SHORT-TERM TOXICITY</b>	
Target/critical effect	ChE depression, cholinergic symptoms
Lowest relevant oral NOEL (mg/kg bw/d)	1 in rats (13-week neurotoxicity study by gavage)
Lowest relevant dermal NOEL (mg/kg bw/d)	No data
Lowest relevant inhalation NOEC (mg/m <sup>3</sup> )	10 in rats (90-day study, highest dose tested)
<b>GENOTOXICITY</b>	
Genotoxicity	Clastogenic <i>in vitro</i> but not <i>in vivo</i> . Interrupts spindle formation <i>in vitro</i> . Overall weight of evidence lies against mutagenicity or genotoxic activity by other mechanisms.
<b>LONG-TERM TOXICITY AND CARCINOGENICITY</b>	
Target/critical effect	Kidney: cloudy swelling of tubules
Lowest relevant NOEL (mg/kg bw/d)	1.8 in 1-year dog study by gavage
Carcinogenicity	Vascular tumours in male mice in a 2-year dietary study at 16 mg/kg bw/d, the lowest dose tested. At the highest dose (1350 mg/kg bw/d), there was also development of renal adenoma and carcinoma in males, while hepatic adenoma and carcinoma became elevated in females.  At the high dose of 420 mg/kg bw/d in a 2-year rat dietary study, there was treatment-related formation of urinary bladder papilloma/carcinoma in both sexes, renal carcinoma and thyroid adenoma/carcinoma in males, and hepatic adenoma in females.
<b>REPRODUCTIVE TOXICITY</b>	
Reproduction target/critical effect	Decreased parental bw gain, bw, feed consumption and conversion efficiency, depressed gestation and lactation bw in rat dams, and increased pup mortality.
Lowest relevant reproductive NOEL (mg/kg bw/d)	4.7 in rats
Developmental target/critical effect	Skeletal and visceral abnormalities in dogs at and above 6.3 mg/kg bw/d in the absence of maternal toxicity.
Lowest relevant developmental NOEL (mg/kg bw/d)	3.1 in dogs
<b>DELAYED NEUROTOXICITY</b>	
Delayed neurotoxicity	No effects

**IMMUNOTOXICITY**

Immunotoxicity	No data
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**DERMAL ABSORPTION**

Dermal absorption	In rats: Up to 2% of applied dose over 30 minutes, rising to a maximum of 25% at 24 hours.  Results obtained with formulated product applied in aqueous carboxymethylcellulose vehicle.  In humans: Up to 4.4% over 4 hours and 16% over 8 hours, applied in acetone vehicle.
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SUMMARY	NOEL	STUDY	SAFETY FACTOR
ADI 0.008 mg/kg bw/d, based on vascular tumour formation.	16 mg/kg bw/d*	2-year dietary study in mice	2000 <sup>#</sup>
ARfD 0.01 mg/kg bw based on ChE inhibition, clinical signs, and reduced bw gain.	1 mg/kg bw/d	13-week neurotoxicity and developmental neurotoxicity studies by gavage in rats	100

\* LOEL value.

<sup>#</sup> The safety factor incorporates a 10-fold component for interspecies extrapolation, a 10-fold component for intraspecies variability, a 5-fold component for adequacy of the database, and a 4-fold component for seriousness of the carcinogenic response. (This 4-fold component comprises a 1-fold factor (low degree of confidence that carbaryl is genotoxic), a 4-fold factor (medium degree of confidence that carbaryl causes malignant tumours) and a further 1-fold factor (metastases not reported)).

**Health value in drinking water**

Health value in drinking water	Current: 0.03 mg/L
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**Metabolism and toxicokinetics**

The absorption, excretion and toxicokinetics of carbaryl are typical of the carbamate class. Carbaryl is extensively absorbed by the oral route and excreted rapidly in the urine by humans and experimental animals except dogs, in which the faeces is also a significant route of excretion. There is little tendency for carbaryl or its metabolites to accumulate in body tissues, even after repeated administration.

**Cholinesterase inhibition**

Carbaryl possesses anticholinesterase activity typical of members of the carbamate class. In rats, ChE inhibition reaches its maximum between 0.5 and 1 hour following carbaryl administration by gavage. The subsequent time course of ChE inhibition is both dose- and tissue-/site-dependent. Recovery of plasma and red blood cell (RBC) ChE activity is rapid (within 2 hours post dosing at 10 mg/kg bw/d and within 24 hours at 50 mg/kg bw/d). At higher doses reversibility is more prolonged.

## Genotoxicity

No new studies were presented for the review. Previous reviews of the genotoxic potential of carbaryl have concluded that carbaryl does not damage DNA and is unlikely to be mutagenic in humans.

## Neurotoxicity and behavioural studies

The effects of carbaryl on the nervous system of rats, chicken, monkeys and humans are primarily related to ChE inhibition and are usually transitory. In a developmental neurotoxicity study, carbaryl had no adverse effects on foetal or pup survival, growth or development at up to and including the highest dose of 10 mg/kg bw/d. In both subchronic and developmental neurotoxicity studies, no adverse findings were made with respect to neuropathology in the adults or offspring.

## Reproduction and development

New developmental studies in rats and rabbits were submitted for the review. Maternotoxicity was seen as cholinergic signs in rats, inhibition of plasma and RBC ChE activity in rabbits, and depressed weight gain in both species, but there were no effects on reproductive parameters. Foetal development was retarded at maternally toxic doses, but there were no treatment-related visceral anomalies or malformations.

## Carcinogenicity

In chronic rodent studies by Hamada (1993a, 1993b), carbaryl caused tumours of the thyroid, urinary bladder and liver in rats, and kidney, liver and vascular systems in mice. However with the exception of the vascular tumours, carcinogenicity did not occur below the highest doses administered (8000 and 7500 ppm in the diet to mice and rats, respectively).

Since carbaryl has not shown any convincing evidence of genotoxic activity, and because the No Observed Effect Levels (NOELs) of 1000 mg/kg bw/d and 1500 mg/kg bw/d were demonstrated in the respective species for bladder, hepatic, thyroid and renal tumours, these high-dose tumours have not been considered a barrier to continuing registration of carbaryl, subject to adequate safeguards that would limit public exposure to the chemical.

However, the vascular system tumours are of significantly greater concern. Although these did not develop in female mice below the 8000 ppm feeding level, they occurred in males even at the lowest dose of 100 ppm. Despite the fact that carbaryl did not cause cancer to develop in a short-term bioassay in genetically engineered male mice that are highly sensitive to genotoxic carcinogens, there are still limitations in the understanding of carbaryl's carcinogenic properties, and its mode or mechanism of action remains uncharacterised. However, because of the development of rare vascular system tumours, it is considered that the use of an enhanced safety factor should be maintained and public exposure should be reduced to the lowest extent reasonably achievable. From the data assessed there is no direct evidence that carbaryl is carcinogenic in humans.

## 3.2 Occupational health and safety

Carbaryl acts by inhibiting ChE enzymes in the blood and central and peripheral nervous systems, and the most sensitive toxicological endpoint in acute and short-term studies is ChE inhibition. For workers exposed to carbaryl seasonally in agricultural and veterinary settings, the dermal NOEL for risk assessment has been set at 20 mg/kg bw/d, based on a 28-day study in rats by dermal administration. No suitable toxicology studies have been performed with carbaryl via the inhalation route, and so the inhalation NOEL of 1.3 mg/kg bw/d was based on the NOEL (1 mg/kg bw/d) of oral 13-week and developmental neurotoxicity studies in rats, adjusting for an inhalation absorption factor of 75%. An acceptable margin of exposure (MOE) for the dermal and inhalation routes was taken as 100.

In addition to uses in agricultural and veterinary settings, carbaryl is also used for pest control around buildings. Because pest control operators (PCOs) are likely to be exposed to carbaryl throughout the year, they must be protected by occupational health and safety (OHS) standards based on long-term toxicology studies. The most significant effect of carbaryl following long-term administration is the formation of vascular system tumours. These occurred in mice during a 2-year study by dietary administration at the lowest administered dose of 16 mg/kg bw/d. Carbaryl does not directly damage genetic material, and will not pose a carcinogenic hazard to humans provided that exposure is constrained to sufficiently low levels. Furthermore, epidemiology studies on farmers and production workers have not provided credible evidence of a causal association between exposure to carbaryl and development of cancer. Accordingly, a dermal Lowest Observed Effect Level (LOEL) for PCOs' exposures has been set to 128 mg/kg bw/d based on the LOEL for tumour formation (16 mg/kg bw/d), adjusted for a dermal absorption factor of 12.5%. The inhalation LOEL was set at 21 mg/kg bw/d, based on the same LOEL for tumour formation, adjusted for an inhalation absorption factor of 75%. To assure protection of PCOs, the acceptable MOE for the dermal and inhalation routes has been set at an enhanced value of 2000 (refer to 'Toxicology hazard profile' in this chapter).

Exposure modelling suggested that even if gloves and chemical-resistant clothing and a full face piece respirator were worn, exposure during preparing (mixing/loading) of WP products for groundboom equipment in broadcast application exceeded the acceptable level. However, exposure can be reduced to acceptable levels if the WP is produced in measured packs of water-soluble packaging (WSP).

For open mixing/loading the SC products for aerial application (up to 550 kg active ingredient /day), even gloves and chemical-resistant clothing are inadequate to assure an MOE  $\geq$  100. Engineering controls (closed mixing/transfer systems) must be considered as a mean of reducing exposure, where the extent of exposure for a mixer/loader wearing overalls and gloves is acceptable for individuals preparing up to approximately 640 kg of carbaryl in SC form. It was recommended that the labels of carbaryl SC products intended for aerial application should be amended to include the relevant engineering controls, and the First Aid Instructions and Safety Directions Handbook (FAISD Handbook) entry for carbaryl SCs retain the Safety Directions to wear overalls and gloves during preparation.

Operators applying carbaryl are likely to be exposed via the dermal route, with the possibility of additional exposure by inhalation. It is not possible to assure the safety of flaggers engaged in aerial spraying operations, unless they are housed within an enclosed cab. However, spray operators applying carbaryl with orchard airblast and groundboom equipment are less heavily exposed due to a lower work rate than with

aerial application, and engineering controls are thus not required. It is also unlikely that pilots in an enclosed cockpit will have appreciable exposure to carbaryl during aerial application.

Exposure of operators preparing (mixing/loading) and applying SC products or WP products in WSP to trees and ornamental plants, grain storage structures and pigs by hand-held spray equipment can be constrained to acceptable levels by gloves and overalls. This use of carbaryl WP products should be discontinued unless WP product can be packed in measured packs of WSP to minimise exposure during preparation (mixing/loading).

Due to the higher MOE necessary to assure the safety of PCOs, predictions based on exposure modelling indicate that even if wearing chemical-resistant clothing and gloves, dermal exposure would be unacceptable when using high-volume powered hand-held spray equipment applying more than about 1.3 kg of carbaryl per day. Consequently, carbaryl applied by high-volume powder hand-held spray equipment (unless by low-volume knapsack applications where the quantity of carbaryl used is below 1.3 kg/d) should no longer be used for pest control in domestic, commercial and industrial situations, with the exception of insect nest eradication.

The continuing veterinary uses of carbaryl in dry soap bar or lotion are supported. The exposure is acceptable where operators wear overall and gloves when applying the soap bar and elbow-length neoprene, nitrile or butyl rubber gloves when applying the lotion.

For the protection of workers re-entering treated crops, re-entry intervals have been set at 8 days for ornamentals and raspberries, 2 days for cotton, 1 day for nursery plants (tree crops in containers) and 1 day for other crops. Persons re-entering and/or re-handling treated crops at prior intervals should wear cotton overalls buttoned at the neck and wrist, and rubber gloves.

### 3.3 Residues and trade

#### Introduction

In 1995 the APVMA initiated a review of the use of carbaryl on cereals. The review at this time was to examine residue data and MRLs related to cereals and animals that may be fed on treated cereal products. An evaluation of the human dietary exposure to carbaryl residues was also conducted after the OCS set up the health standards ADI and ARfD.

In evaluating the human dietary exposure to carbaryl residues it was necessary to examine the intake from consumption of food commodities. To do this, National Estimated Daily Intake (NEDI) and National Estimated Short-Term Intake (NESTI) calculations were undertaken. NEDI and NESTI calculations were re-conducted based on Food Standards Australia New Zealand's (FSANZ) 2009 revision of consumption figures, rather than the 1995 consumption data used in the previous report. New methodology for determination of carbaryl residues in animal tissues has also been incorporated in this report. These resulted in revised recommendations and amended MRLs to cover uses of carbaryl in agricultural situations.

## Maximum residue limits for cereal uses

Carbaryl was registered for both pre- and post-harvest on cereal grains. Following calculations of NESTI based on the 2009 FSANZ revised consumption data, post-harvest use on cereal grains is no longer acceptable (NESTI > 100%) but pre-harvest use is confirmed acceptable.

The current harvest WHP for cereal grains of 0–3 days was not supported by sufficient data. As 14 days after the last spray is the first time point for which an adequate number of samples were collected for the major cereal grains, the harvest WHP for cereal grains was extended to 14 days. Maximum residues resulting from only pre-harvest use of carbaryl were used to derive an MRL for pre-harvest use. Using a 14-day WHP, the residues data suggest that the MRL for cereal grains should remain at 5 mg/kg except for barley, rice and sorghum at 15, 7 and 10 mg/kg respectively.

The processed cereal commodities for which residues were found to concentrate to a significant extent and for which separate MRLs are required are sorghum bran, wheat bran and rice hulls. To cover the maximum expected residue in wheat bran, the MRL for wheat bran is advised to be decreased from 20 mg/kg based on pre- and post-harvest uses to 10 mg/kg. Likewise an MRL of 20 mg/kg for sorghum bran (decreased from 50 mg/kg previously advised) is recommended. An MRL of 15 mg/kg is established for rice hulls.

## Animal feed commodities

Carbaryl-treated crops may be fed to animals, leading to residues in animal tissues and milk. At the time of the review the MRLs in Table 4 of the MRL Standard (MRLs for pesticides in animal feed commodities) were:

- Forage of cereal grains T100 mg/kg
- Straw and fodder (dry) of cereal grains T100 mg/kg (where 'T' is 'temporary').

These MRLs did not adequately cover the range of possible animal feed commodities for which carbaryl is currently approved for use. To remedy this situation new MRLs were recommended for a variety of animal feeds.

Pasture is grown as forage or hay for feeding to animals. An MRL of 300 mg/kg for hay or fodder (dry) of grasses is required to adequately cover natural variation in residue results when combined with a WHP of 7 days for cutting for stock food. An appropriate MRL for grass pasture (green) would be 100 mg/kg when expressed on a wet weight basis or 400 mg/kg when expressed on a dry weight basis using the assumption that pasture contains 25% dry matter.

The change in harvest WHP for cereal grains also required a change in the WHP for grazing/cutting for stock food. When a 14-day WHP for grazing/cutting for stockfeed is used for cereal grains, an MRL of 100 mg/kg adequately covers residues in straw and fodder (dry) of cereal grains. Residues in forage crops (dry weight basis) are also covered by an MRL of 100 mg/kg for cereal grain forage when combined with a 14-day WHP.

Legume crops are sometimes grown as animal feeds (succulent crops) or the waste left after the harvesting of grain is fed to animals (fodder/hay). The residue data supported an MRL of 400 mg/kg (wet weight basis) for legume forage (green) and 100 mg/kg (dry weight basis) for legume fodder when combined with a 7-day WHP.

On examining the data for miscellaneous forage and fodder crops, it was apparent that the current grazing WHP of 3 days could lead to residues in excess of 400 mg/kg (on a dry weight basis) and therefore violations of Australian animal tissue MRLs. The grazing WHP for miscellaneous fodder and forage crops was extended to 7 days to afford the necessary margin of safety against residue violations in animal tissues. In addition, an MRL of 300 mg/kg was recommended to apply to crops classified under the FAO/WHO Codex Alimentarius Commission (Codex) crop grouping AM 0165 viz miscellaneous fodder and forage crops (except leguminous and grassy plants (Gramineae), but including grasses for sugar production).

### Animal commodities

Carbaryl was registered as a direct treatment for pigs. Literature evidence indicated that direct treatment of pigs resulted in negligible residues. Uses of carbaryl products as direct treatments on poultry were cancelled in January 2007 as an outcome of Part 1 of the carbaryl review as the APVMA was not satisfied that the use of the products would not result in residues in poultry commodities exceeding the MRLs established.

Therefore the MRLs for mammalian commodities can be set based on estimated exposure to residues in the animal diet and from animal transfer studies that determine residues in tissues and milk after feeding at different levels. The maximum feeding level, based on the revised MRLs for animal feed commodities, is estimated to be approximately 400 ppm for cattle and was used in assessing the animal MRLs. The Codex MRLs established for mammalian tissues and milk were also based on feeding forage and fodder crops at 100 mg/kg fresh weight (400 mg/kg when expressed on a dry weight basis). As the Australian MRLs were set based on the same maximum feeding level, there is minimal risk of violations of the relevant Codex MRLs.

Since the APVMA review began, new methodology for the determination of carbaryl residues in animal tissues has been considered by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). The new method analyses parent carbaryl and conjugated carbaryl. Rat metabolism studies reviewed by the JMPR indicate that most of the parent carbaryl present in urine is in conjugated forms.

The Australian animal commodity MRLs were therefore revised to include parent carbaryl and conjugated carbaryl used in the Codex MRLs. It is also recommended to revise the Australia residue definition for carbaryl in animal commodities to:

Commodities of animal origin: Sum of carbaryl and conjugates, hydrolysed to carbaryl, expressed as carbaryl.

Based on the new methodology, the maximum residue in edible offal was estimated up to be 2.3 mg/kg. The MRL for edible offal (mammalian) of 0.2 mg/kg recommended in previous review report will be inadequate to

cover residues in liver and kidney. An MRL of 3 mg/kg is appropriate for edible offal (mammalian). The MRLs for both whole milk and meat (mammalian) of 0.02 mg/kg recommended in the previous report were too low. These MRLs were amended to 0.1 mg/kg and 0.07 mg/kg respectively.

Previous assessment of poultry commodity MRLs were based on metabolism studies and the previous recommendations remain appropriate.

These changes in MRLs and carbaryl definition do not constitute a significant change in the previously assessed risk to trade. The actual likelihood of occurrence of total carbaryl residues is not changed as the use pattern has not changed.

## Dietary intake

The review of toxicology information recommended an increase in the ADI from 0.004 mg/kg bw/day to 0.008 mg/kg bw/day. In addition an ARfD of 0.01 mg/kg bw/day was established for carbaryl.

## Chronic dietary exposure

The chronic dietary exposure to carbaryl is estimated by the NEDI calculation encompassing all registered and temporary uses of the chemical and the mean daily dietary consumption data derived from the 2009 FSANZ revision of consumption figures. The NEDI calculation is made in accordance with World Health Organization Guidelines<sup>1</sup> and is a conservative estimate of dietary exposure to chemical residues in food. The re-calculated NEDI for carbaryl is confirmed to be < 20% of the ADI.

Dietary Modelling Of Nutritional Data (DIAMOND) for chronic dietary exposure of carbaryl was also performed. The DIAMOND model confirmed the chronic dietary exposure of carbaryl as < 20% of the ADI for the general population.

In 2003 the 20th Australian Total Dietary Survey<sup>2</sup> was published. This survey included carbaryl in the testing performed and calculated that the mean estimate dietary exposure to carbaryl ranged from 0.85% of the ADI for adults to 5.27% of the ADI for toddlers (2 years old). This confirms that chronic dietary exposure to carbaryl does not represent an undue health risk to consumers.

## Short-term dietary exposure

Acute dietary exposure is estimated by the NESTI calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data. NESTI calculations are conservative estimates of acute exposure (24-hour period) to chemical residues in food.

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1 Guidelines for predicting dietary intake of pesticide residues, WHO (1997).

2 Available from the FSANZ website at:  
[www.foodstandards.gov.au/scienceandeducation/publications/20thaustraliantotaldietsurveyjanuary2003/](http://www.foodstandards.gov.au/scienceandeducation/publications/20thaustraliantotaldietsurveyjanuary2003/).

The NESTI calculations were revised in line with the 2009 FSANZ revision of consumption figures. It was found that previous outcomes of NESTI calculations were confirmed acceptable except for those for raspberries and post-harvest use on cereals. The use on raspberries can be supported provided the harvest WHP is increased to 7 days. The use of carbaryl on cereal grains is no longer supported, as discussed above.

Of the crops and commodities on which continued uses are supported and for which an MRL were established, the NESTI calculations based on MRLs do not exceed the ARfD for the following:

- raspberries (WHP extended to 7 days from 3 days previously recommended)
- grapes, for control of cutworms by application to vine base
- citrus (orange and lemon only) (WHP 3 days)
- tropical fruits, but only where it is used on non-flowering, and non-fruit-bearing trees or bushes
- avocados (WHP 3 days)
- mangoes (WHP 7 days)
- pomes (apples and pears) (WHP 11 weeks)
- loquats (spray up to fruit size 10 mm) (WHP is not required when used as directed)
- stone fruit (except cherries) (WHP 5 weeks)
- pre-harvest use on cereal grains (WHP 14 days)
- animal commodities
- animal feeding commodities (WHP 7 days)
- beetroot, potatoes/sweet potato, turnip (swede) (WHP 3 days)
- tree nuts (macadamia nuts, pecan nuts)
- cottonseed (WHP 3 days)
- oilseeds (except cottonseed) after storage in carbaryl treated storage structures
- cucurbits (including melons) but only when used up to time of flowering
- pulse after storage in carbaryl treated storage structures

Further details can be found in Chapter 4.

## Changes to Maximum Residue Limits Standards

A number of changes are recommended to the current MRLs for a number of commodities. The details of these changes can be found in Chapter 5.

## Withholding periods

The assessment highlighted that changes were required to WHPs on relevant labels, the details of which can be found in Chapter 4.

## Summary review findings from the assessment of residue data

A summary of the residue assessment, in particular residues data and acute dietary intake, is tabulated in Table 8. In summary, Table 8 lists all label uses and whether they were to be retained or needed amendment, or whether use patterns needed to be cancelled.

**Table 8: Summary of available residues data and dietary exposure assessment**

CROP	USES TO BE RETAINED	USES TO BE CANCELLED	WHP (DAYS)	COMMENTS
TREE AND VINE CROPS				
Avocados	All	None	3	Commodities with sufficient data and where exposure < ARfD.
Citrus	Oranges and lemons only	All other citrus, including grapefruit, tangelos, tangerines, mandarins	3	Insufficient residues data to establish MRL except oranges and lemons.
Feijoa, guavas	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	An MRL of 0.01 mg/kg is included for effective control of use (uses restricted.)
Fruit—general	None	All		Insufficient residues data to establish MRL.
Grapes	Use for cutworm when applied around base of vine.	All other foliar uses	NR	Dietary exposure exceeds ARfD and uses restricted.
Jaboticaba, Jackfruit	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	An MRL of 0.01 mg/kg is included for effective control of use (uses restricted).
Kiwifruit	None	All	–	Insufficient residues data to establish MRL.

CROP	USES TO BE RETAINED	USES TO BE CANCELLED	WHP (DAYS)	COMMENTS
Loquats	Use for fruit thinning, up to fruit size 10 mm	All other uses	NR	An MRL of 0.2 mg/kg is included for pome and exposure < ARfD.
Litchis	Use on non-flowering/non-fruiting trees	Use on fruit bearing trees	NR	An MRL of 0.01 mg/kg is included for effective control of use (uses restricted).
Macadamias	All	None	0	Commodities with sufficient data and where exposure < ARfD.
Mangoes	All	None	7	Commodities with sufficient data and where exposure < ARfD.
Pecans	All	None	0	Commodities with sufficient data and where exposure < ARfD.
Pome fruit: apples, pears (for loquats see above)	All	None	77	Commodities with sufficient data and where exposure < ARfD (MRL 0.2 mg/kg).
Rambutans	Use on non-flowering/non-fruiting trees	Use on trees bearing fruit	NR	An MRL of 0.01 mg/kg is included for effective control of use (uses restricted).
Stone fruit: apricots, plums, prunes, peaches, nectarines	All (except cherries)	Cherries	35	Commodities with sufficient data and where exposure < ARfD, except cherries.
<b>FRUIT AND VEGETABLE CROPS</b>				
Beans	None	All		Dietary exposure exceeds ARfD.
Blueberries	None	All	–	Insufficient residues data to establish MRL.
Cape gooseberry	None	All	–	Insufficient residues data to establish MRL.
Capsicum	None	All	–	Dietary exposure exceeds ARfD.
Carrots	None	All	–	Insufficient residues data to establish MRL.
Cucurbits	Melons and other flowering cucurbits, up to time of flowering	All other uses on cucurbits	–	Dietary exposure exceeds ARfD and uses restricted before flowering.
Leafy vegetables	None	All	–	Dietary exposure exceeds ARfD.
Potatoes	All	None	3	Commodities with sufficient data and

CROP	USES TO BE RETAINED	USES TO BE CANCELLED	WHP (DAYS)	COMMENTS
				where exposure < ARfD.
Sweet potato	All	None	3	An MRL of 0.1 mg/kg is set based on potatoes data.
Raspberries	All	None	7	Commodities with sufficient data and where exposure < ARfD.
Root vegetables	Beetroot, turnips (swede)	All other	3	Commodities with sufficient data and where exposure < ARfD for beetroot and turnips (swede).
Strawberry	Non-fruiting runner production	All uses on flowering or fruiting plants	NR	Insufficient residues data to establish MRL and uses restricted to non-fruiting runners.
Tomatoes	None	All		Dietary exposure exceeds ARfD.
Vegetables—general	None	All		Dietary exposure exceeds ARfD.
<b>FIELD CROPS AND PASTURES</b>				
Cereals (pre-harvest uses)	All	None	14	Commodities with sufficient data and where exposure < ARfD.
Cereals stored grain	None	All	–	Dietary exposure exceeds ARfD.
Cotton	All	None	3	Commodities with sufficient data to establish MRL and where exposure < ARfD.
Duboisia (non-food uses)	All	None	1 (G)	No residues data for edible portions (use restricted).
Kenaf (non-food uses)	All	None	1 (G)	No residues data for edible portions (use restricted).
Linseed	None	All	–	Insufficient residues data to establish MRL.
Lucerne	All	None	7 (G)	Commodities with sufficient data and where exposure < ARfD.
Maize	All	None	14	Commodities with sufficient data and where exposure < ARfD.
Pastures, pasture seed crops	All	None	7 (G)	Commodities with sufficient data and where exposure < ARfD.
Rice	All	None	14	Commodities with sufficient data and where exposure < ARfD.

CROP	USES TO BE RETAINED	USES TO BE CANCELLED	WHP (DAYS)	COMMENTS
Rosella	All	None	–	Commodities with sufficient data and where exposure < ARfD.
Sorghum	All	None	–	Commodities with sufficient data and where exposure < ARfD.
Sunflower	None	All	–	Insufficient residues data to establish MRL.
Sweet corn	None	All		Dietary exposure exceeds ARfD.
<b>ANIMAL TREATMENT</b>				
Pigs	All	None	7	Commodities with sufficient data and where exposure < ARfD.

NR Not required when used as directed.

G Graze.

### 3.4 Overseas regulatory status

#### Joint FAO/WHO Meeting on Pesticide Residues

Carbaryl was reviewed by the JMPR in 1963, 1965, 1966, 1967, 1969, 1973, 1996, 2000, 2001, 2002 and 2007. The original ADI of 0–0.02 mg/kg bw/d was set in 1963 on the basis of a No Observed Adverse Effect Level (NOAEL) of 1.8 mg/kg bw/d in a 1-year dog study. This was revised to 0–0.01 mg/kg bw/d in 1969 because of concern about effects on the male reproductive system seen in a 1-year gavage study in rats with a NOAEL of 2 mg/kg bw/d, and because a dose of 0.12 mg/kg bw/d may have affected renal function observed in a 6-week study in humans. In 1973, the JMPR established a full ADI of 0–0.01 mg/kg bw/d.

The JMPR carried out a further toxicological review of carbaryl in 1996, and decreased the ADI to 0.003 mg/kg bw/d by application of a 5000-fold safety factor to the LOEL for vascular tumours in male mice. The JMPR again considered carbaryl in 2001 when the ADI was revised upwards to 0.008 mg/kg bw/d; while the basis for the ADI was unchanged, the safety factor was relaxed to 2000. The JMPR also established an ARfD for carbaryl of 0.2 mg/kg bw, based on an NOAEL for ChE inhibition of 125 ppm (equal to 3.8 mg/kg bw/d) in a 5-week dietary study in dogs. A safety factor of 25 was applied because ChE inhibition by carbaryl (in rats) is 'rapidly reversible and driven by the peak concentration in plasma'.

Further metabolism, environmental fate, good agricultural practice (GAP) and residues data were considered at the JMPR 2002 meeting. International Estimated Daily Intakes for five regional diets ranged from 10% to 60% of the ADI. The meeting concluded that the intake of residues of carbaryl resulting from those uses considered by JMPR was unlikely to present a public health concern. However, the meeting concluded that the dietary acute intake of grapes by children and adults and of apricot, cherries, peaches and plums by children could exceed the ARfD, based on the information provided. For all the other commodities

considered, the meeting concluded that short-term intake of residues of carbaryl in these commodities, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

At the 2007 JMPR meeting, residue data were presented for the use of carbaryl on chilli pepper and cranberries. The meeting concluded that the long-term and short-term intake estimates derived from residues of carbaryl use on cranberries and chilli peppers were unlikely to present a public health problem.

### United States Environmental Protection Agency

In October 1996, the United States Environmental Protection Agency (US EPA) imposed exposure mitigation measures on carbaryl-based products. Pending the submission of user exposure studies to the agency, approval was suspended for use of dust formulations on trees and ornamental plants where application was intended to be higher than chest height, and some applications to pets. The conditions of use of household liquid and dust products were amended to prohibit use more than once per week, and to mandate that gloves be worn during application.

In June 2003 the US EPA released an Interim Re-registration Eligibility Decision (IRED) for carbaryl. The report stated that 'although all uses of carbaryl may not meet current safety standards and some uses may pose unreasonable risks to human health and the environment these effects could be mitigated'.

In March 2005, additional toxicology, worker exposure monitoring and environmental fate data were requested, including acute toxicity and product chemistry data for all pesticide products containing carbaryl; these data were to be used for changes to product labels. In response to the data call-in, many carbaryl registrants chose to voluntarily cancel their carbaryl products rather than revise their labels or conduct studies to support these products.

In September 2007 the US EPA released the Reregistration Eligibility Decision (RED) for carbaryl. The carbaryl human health risk assessment was revised to incorporate new data and new methodologies, update use information and recent residue data, and incorporate other new information obtained from public comments to the IRED.

The report supported the continued registration of carbaryl products. US EPA's revised dietary risk assessment for food showed that acute dietary exposure to carbaryl residues in food were found to be below the US EPA's level of concern and comprised < 100% of the acute population adjusted dose (aPAD) at the 99.9th percentile of exposure.

The US EPA's RfD is 0.008 mg/kg bw/d, in accordance with the JMPR level outlined in the section 'Joint FAO/WHO Meeting on Pesticide Residues' above. (As is recommended in this Final Review Report and Regulatory Decision, the ADI for Australia as set by the OCS has been revised from 0.004 mg/kg bw/d to 0.008 mg/kg bw/d in accordance with the relaxing of the safety factor to 2000.)

The US EPA's ARfD is 0.01 mg/kg/d. The ARfD was based on a NOAEL of 1 mg/kg/d in a rat developmental neurotoxicity study, to which an uncertainty factor of 100 was applied. The US EPA did not evaluate dietary risk for chronic exposure to carbaryl due to the rapid reversibility of cholinesterase inhibition, the toxicological endpoint of concern.

In August 2008 the occupational exposure assessment was finalised. All seedling drench/dipping use, wheat, pets (except for pet collars) and all pet-related uses were cancelled. All dust (for use on agriculture) and dry flowable formulations were cancelled and aerosol can formulations were prohibited. All WP formulations must be packaged in WSP. Turfgrass uses were limited to golf courses, sod farms, cemeteries and commercial landscapes only, unless limited to spot treatments of less than 1000 square feet. Personal protective equipment (PPE) for uses and re-entry intervals for treated crops were recommended.

### **United Kingdom Department of Environment, Food and Rural Affairs report, September 1996**

An initial review conducted in 1996 by the United Kingdom identified toxicological concerns about workers' exposure to carbaryl. At this time regulatory actions taken included the:

- revocation of use in poultry houses
- prohibition of application via hand-held or similar equipment
- revocation of home garden uses of carbaryl
- modification to application equipment
- strengthening of protective equipment requirements on labels.

In 1998 the United Kingdom began a review of anticholinesterase compounds that included examination of carbaryl. Registrants were not prepared to support the continued registration of carbaryl through such a review and therefore all carbaryl products were phased out.

### **European Union**

At the time of the preparation of this report carbaryl was not included in the European Union's Annex 1 for plant protection products and there were no national-level authorisations in place. The final review report (September 2006) recommended against the inclusion of carbaryl on the grounds that the information available was insufficient to satisfy requirements in regard to consumer exposure assessment and data on the toxicity of breakdown products. The identified concerns related to the potential carcinogenic properties of carbaryl, and high risks to terrestrial and aquatic organisms.

The ADI was set at 0.0075 mg/kg bw/day (safety factor of 2000) and the ARfD as 0.01 mg/kg bw/day (safety factor of 100).

### 3.5 Summary of public submissions

In response to the release of the carbaryl PRF report Part 2 for products used in agricultural situations, the APVMA received submissions from a number of industry groups, state authorities and registrants about the proposed findings. Specific issues raised in response to the recommendations in the PRF report are detailed below.

#### General comments

The APVMA received comments from AG & HC Mason of South Australia regarding the importance of carbaryl for the control of cherry slugs and earwigs, and in apple thinning. These comments have been noted and the APVMA advises that these uses will be retained on the label.

#### Submissions on the residues assessment

The APVMA received submissions to the review about the residues assessment from:

- the Australian Mango Industry Association Limited
- Avocados Australia
- Horticulture Australia Limited (HAL)
- the Queensland Department of Agriculture, Fisheries and Forestry .

#### *Australian Mango Industry Association Limited, Avocados Australia and Horticulture Australia Limited*

##### WITHHOLDING PERIODS FOR MANGOES AND AVOCADOS

The submissions from the Australian Mango Industry Association Ltd, Avocados Australia and HAL raised concerns regarding the need for extension of the WHPs for mangoes and avocados. The PRF report recommended that uses of carbaryl products on mangoes and avocados only be allowed up to flowering. This recommendation was based on the lack of available data to establish a shorter WHP. This issue has been addressed by the submission of additional residue data to the review for mangoes and avocados. These data have resulted in the establishment of a 3-day WHP for avocados and a 7-day WHP for mangoes.

#### *NSW Environment Protection Authority*

##### CLARIFICATION ON TIMING OF APPLICATION FOR NON-FLOWERING/NON-FRUITING TREES

The NSW Environment Protection Authority (NSW EPA) requested clarification of Section 5.1.4 in Volume 1 of the PRF report regarding the restricted application of carbaryl products on certain tree crops to non-flowering and non-fruiting trees. The NSW EPA requested advice on what would be considered a flowering

tree. The NSW EPA also requested that a more concise label statement be considered to avoid user confusion.

The APVMA noted the NSW EPA's comments and consulted industry groups regarding the wording of the label statement. The APVMA retained the instruction of 'non-flowering and non-fruiting trees'.

### *Queensland Department of Agriculture, Fisheries and Forestry*

#### ESTABLISHMENT OF WITHHOLDING PERIOD BASED ON RESIDUE DATA

The Queensland Department of Agriculture, Fisheries and Forestry (QDAFF) commented that the extension of WHPs because of insufficient residue data was contrary to GAP, as the WHP has been set based on residue consideration rather than the conditions to control the pests. The QDAFF suggested that consideration should be given to the efficacy of the treatment regime because changes to the WHP could result in the uses of the product becoming inefficacious to treat certain pests and therefore these uses should be removed from labels.

It is noted that MRL and WHP combinations are established in line with GAP. However, in some cases the residue data do not support the proposed MRL–WHP combination. A number of eventualities may cause this, including the lack of residue data at the proposed or desired WHP or the proposed MRL not being compatible with acceptable dietary exposure. In any case, it is not the WHP per se that determines the efficacy of the application.

The APVMA considered removing some uses from the labels based on the longer WHPs but advice received from various industry groups indicated that the chemical was used at different times during the growing season and therefore the retention of these uses was necessary. Industry noted that there were longer WHPs for some commodity groups and advised the APVMA that carbaryl products could be used in association with other chemicals to manage crop pests. The APVMA has therefore retained uses with longer WHPs on labels.

#### COMBINING PRE- AND POST-HARVEST USE IN THE SETTING OF MRLS

The QDAFF questioned the setting of the MRL on cereals; they commented that the PRF report indicated that high residues from the pre- and post-harvest uses were combined to produce the MRL. The QDAFF commented that, in a normal assessment of residues data, the assessment should set an MRL that would cover somewhere between the 90th and 99th percentile of residues produced according to GAP. The QDAFF felt that summing the two high residues produces an MRL estimate that is improbable in normal practice because it is considered a statistical improbability that the crop with a high residue from the pre-harvest use would also get the high residue from the post-harvest use. The QDAFF believed that summing the high residues in this way to set an MRL results in the percentile of residues covered by the MRL being excessive, leading to the MRL being set at an artificially high level.

The QDAFF suggested that high residues should be combined by probabilistic modelling of the combined residue data sets in order to get a reasonable estimate of the MRL. The QDAFF commented that an MRL of

15 mg/kg is excessive. It was also requested that the APVMA detail the percentile of residues that the MRL should cover and the percentile of residues that the summation does cover.

The APVMA establishes MRLs to cover the maximum GAP. The post-harvest uses on stored cereal grains were not supported after NESTI calculation based on 2009 FSANZ revision of consumption figures was conducted. The MRLs were reassessed and revised based on the residual data of pre-harvest uses only.

#### ROSELLA AND KENAF

The QDAFF noted that the executive summary in the PRF report indicated that rosella and kenaf are not used as foods. The QDAFF commented that as rosellas can be used in jams and kenaf are edible hibiscuses, they may be used as foods.

APVMA notes the QDAFF's concerns that rosella and kenaf may be used as foods. However, no residue data are available to establish MRLs for these commodities. The APVMA has therefore added a restraint to the labels of products registered for use on rosella and kenaf to restrict uses to crops not intended for human consumption.

### Submissions on the toxicology and occupational health and safety assessments

The APVMA received submissions to the review about the toxicology and OHS assessments from:

- the Queensland Department of Agriculture, Fisheries and Forestry
- the NSW Environment Protection Authority
- the Australian Mango Industry Association Limited
- Avocados Australia
- Horticulture Australia Limited
- Kendon Chemicals.

#### *Queensland Department of Agriculture, Fisheries and Forestry*

##### RE-HANDLING VS RE-ENTRY PERIODS

The QDAFF commented that 're-entry periods on labels are confusing because they seek to include both the risk associated with merely re-entering a crop and the risk from occupationally handling treated produce'. The QDAFF suggested that labels need to have both a re-entry period and re-handling periods to avoid confusion.

The APVMA consulted with nursery industry representatives regarding the need for both re-entry and re-handling statements on labels. It was determined that the statement more specific for nursery plants could be included on the label to clearly differentiate between nursery plants and ornamental crops and plants. The APVMA has therefore included a re-entry/re-handling statement on the label for nursery plants.

#### PROPOSED 8-DAY RE-ENTRY PERIOD FOR ORNAMENTALS

The QDAFF indicated that the long re-entry period of 8 days for ornamentals would not be observed by the nursery industry. It was also advised that in most instances the public have access to the treated areas often before the spray has dried and it is unlikely that they will have access to PPE.

The OCS advised that the re-entry period was recommended in the PRF report based on the international guidelines for calculating re-entry periods, which is calculated after consideration of dislodgeable foliar residues (DFRs), activity to be performed and half-life of carbaryl residues.

The OCS considers that nursery trees planted in pots are tree crops since they can grow up to 2–3 metres and that handling of pots is a low-exposure activity. Hence the recommended 1-day re-entry interval would apply.

As regards public exposure, the public do not have access to the registered label for carbaryl products and, as such, should not be allowed to enter the treated areas. A sign or placard should be displayed outside the nurseries indicating the risk associated with entry during these 8 days.

Consultation with nursery representatives indicated that retail nurseries are not likely to use agricultural products whereas those production nurseries that may use agricultural carbaryl products do not have members of the public accessing the growing areas.

#### ***NSW Environment Protection Authority***

##### ENCLOSED TRANSFER/MIXING SYSTEMS

The NSW EPA advised that the wording in Section 5.1.4 in Volume 1 of the PRF report could be reworded to make the statement clearer. The APVMA has considered this advice and amended the statement in this final report.

The NSW EPA has requested clarification on what constitutes 'enclosed transfer/mixing systems' as there are many definitions in the industry. The APVMA considers that:

A 'closed transfer/ mixing system' is a system that takes the pesticide out of its container and transfers it to the spray tank automatically without the need to measure the chemical manually. There are different types of closed systems that are commonly used by industry, particularly for loading aircraft for aerial application. As a closed system is only required for aerial application, the industry has indicated that the requirement will be understood.

## ENGINEERING CONTROLS

The NSW EPA requested clarification of the statement under Section 5.1.7 regarding what is considered to be 'engineering controls' and whether this statement would be understood by users in different industries.

'Engineering controls or enclosed cabs' include places in which users/flaggers can sit and be protected while pesticides are being applied. The term can include the cockpit of a crop duster. It can also be a closed cab on a tractor. Or it might be a truck or car with the windows and doors closed. Pesticide applicators, pilots, and flaggers can protect themselves by using enclosed cabs.

### *Australian Mango Industry Association Ltd and Avocados Australia*

The Australian Mango Industry Association Ltd and Avocados Australia both raised similar issues regarding use of carbaryl in mangoes and avocados. These are outlined below.

## COMMENTS ON AIRBLAST VS AERIAL MIXING/LOADING

The OCS advised in the PRF report that only 15 kg of carbaryl would be handled in the airblast method of application and not the higher work rates associated with aerial application. The lower amount of carbaryl handled should not require only enclosed transfer mixing systems for orchard airblast application.

The OCS commented that, in the PRF report of carbaryl Volume 2, Table 12 indicates that for WP formulations, MOEs are acceptable for dermal exposure for mixing/loading 15 kg of carbaryl. Inhalation exposures for WP formulations are given in tables 14 and 15. The risk is unacceptable without respiratory protection. MOEs are acceptable if a half-facepiece respirator is worn. Therefore, closed mixing/loading is not required for airblast mixing/loading. However, a half-face piece respirator along with cotton overalls and gloves should be worn for this scenario (WP products not packed in WSP). Open mixing/loading for broadacre use of WP product is not recommended as indicated in Table 15 (PRF report, Volume 2, page 66) and therefore it is best that WSP is used (250 g/500 g/1 kg packs) for WP products.

For SC products, cotton overalls and gloves are required for mixing/loading for airblast applications and groundboom equipment for broadacre applications. For aerial applications quantities of the active required could be large (up to 550 kg), and risk to workers is acceptable only with closed mixing/loading (Table 20, PRF report, Volume 2, page 69). Therefore, only closed mixing/loading (engineering control) will be recommended for aerial application. The report has been amended accordingly.

## CARBARYL APPLICATION METHODS

The two industry groups questioned the need for operators to be protected by engineering controls when applying carbaryl by ground application. It was suggested that additional PPE requirements would be sufficient to generate acceptable exposures as an alternative to engineering controls.

The OCS advised that Scenarios 5 and 6 in *Volume 2: Toxicology and OHS report* conclude that spray operators applying carbaryl with orchard airblast and groundboom equipment do not require engineering

controls (enclosed cabs) to protect them. Cotton overalls and gloves are recommended during application by the airblast method. It should be noted that open mixing/loading for SC products required for broadacre usage can be mixed wearing overalls and gloves.

The OCS agrees that detailed exposure modelling and various scenarios are confusing. In summary, WP formulations require WSP and, for aerial mixing/loading, closed systems should be used for mixing/loading.

#### RE-ENTRY PERIODS FOLLOWING CARBARYL APPLICATION

This comment referred to the proposed 5-day re-entry period for mangoes. This re-entry period was recommended based on the international guidelines for calculating re-entry periods, which is calculated after consideration of DFRs, activity to be performed, and half-life of carbaryl residues. These periods are for workers only. It is not that workers cannot enter the treated orchards; it means that if re-entry is required before 5 days have elapsed, workers are required to wear cotton overalls and gloves. However, a re-entry period of 1 day was set for all tree crops including mangoes based on the more likely low-exposure activities such as irrigation and scouting. Note that the WHP for harvesting mangoes (7 days) is longer than the re-entry period (5 days) for high-exposure activities (pruning, thinning) as recommended in the PRF report.

#### *Horticulture Australia Limited*

#### CHANGES TO MIXING/LOADING

Similarly to the mango and avocado industry comments, HAL noted that only 15 kg of carbaryl will be handled in the airblast method of application.

The OCS commented that, in the published PRF report, Volume 2, tables 12, 17 and 18 indicate that for WP and SC formulations, MOEs are acceptable for dermal exposure for mixing/loading 15 kg of carbaryl. In addition, inhalation exposures for WP formulations (which is a worst case scenario when compared with SC formulation) are given in tables 14 and 15. The risk is unacceptable without respiratory protection but is acceptable if a half-face piece respirator is worn. Therefore, closed mixing/loading is not required for airblast mixing/loading (either WP or SC formulations). However for WP formulations, a half-face piece respirator, along with cotton overalls and gloves, should be worn. For SC formulations, cotton overalls and gloves are required for mixing/loading for airblast applications.

#### APPLICATION METHODS FOR SC PRODUCTS

Scenarios 5 and 6 in *Volume 2: Toxicology and OHS report* concluded that spray operators applying carbaryl with orchard airblast and groundboom equipment do not require engineering controls (enclosed cabs) to protect them. Cotton overalls and gloves are recommended for SC products during application by airblast method.

## RE-ENTRY PERIODS

HAL requested clarification on the calculation of re-entry periods. HAL raised concerns regarding the conservative re-entry intervals and believed it may be due to overestimate of the MOEs. HAL noted that the overestimate of the MOEs may have arisen due to the use of transfer coefficients (TCs) that are too high for the type of work practices being undertaken.

The OCS advised that for calculations of re-entry periods when the following formula is used [dermal dose = (DFR levels x TC x 8) / bw where TC is the transfer coefficient and the workday is 8 hours], initial DFR levels are taken as 20% of the application rates, which is the default used in the US Re-entry Calculator. The summarised study values are not taken into account as the study is a turf study, which is not relevant for macadamia nuts and avocados. The OCS agrees with the comment that the activity for macadamia nuts and avocados will be irrigation and scouting and that the TC of 1000 used in the report is excessive. The report has been amended accordingly and the TC value of 500 is used. The re-entry period will become 1 day for avocados, macadamia and other tree crops.

## *Kendon Chemicals*

### HOW WAS THE ACUTE ORAL TOXICITY LD<sub>50</sub> VALUE IN RATS CHOSEN?

Kendon requested advice on how the value 246 mg/kg was chosen and whether the study that produced it used appropriate methodology to current standards and could the Acute Oral Toxicity LD<sub>50</sub> (rat) value or range from validated sources be published as it should be used for classification purposes under Dangerous Goods and Hazardous Substances Regulations.

The OCS advised that the PRF report, under Section 1.4.5 in Volume 2 (page 28), states that technical grade carbaryl has a worst acute oral LD<sub>50</sub> of 246 mg/kg bw in rats. The studies assessed by the OCS do meet the appropriate methodology. It is the OCS's policy to list the worst LD<sub>50</sub> and use the same for classification purposes under Dangerous Goods and Hazardous Substances Regulations. It should be noted that the OCS has extrapolated acute oral toxicity for products containing 160 g/kg or less of carbaryl to have an oral LD<sub>50</sub> of 1500 mg/kg bw or greater. This complies with the cut-off value specified by the APVMA for domestic pesticide formulations.

### CLARIFICATION REGARDING OCCUPATIONAL HEALTH AND SAFETY ISSUES IN SECTION 3.2, VOLUME 1 OF THE PRELIMINARY REVIEW FINDINGS REPORT

Kendon raised concerns that the main basis for the change in controls for carbaryl in the review are the oral vascular system tumours in male mice at a LOEL of 16 mg/kg bw/d and the LOEL of 21 mg/kg bw/d determined for inhalation (based on the oral vascular system tumours). The 16 mg/kg bw/d figure with a 2000-fold safety factor gives rise to an ADI of 0.008 mg/kg bw/d (which is in line with JPMR; see PRF report, Volume 1, pages 19 and 20). It was noted that, considering that the review emphasises no credible epidemiological evidence of harm, there is no specific detail to then justify why the male mice tumour data should be taken in account, given the statement about the epidemiology of farmers and production workers over the period since 1960 when the product started to be produced. The review does not adequately justify

following the JPMR ADI value of 0.008 mg/kg bw/d. Additionally, Kendon requested clarification as to why a study using the oral route of administration was chosen for the ADI given the exposure is likely to be dermal.

It should be noted that for the OHS assessment of seasonally exposed workers in agricultural settings and re-entry intervals the study used to establish a suitable exposure level was a dermal exposure rat study. For PCOs likely to be exposed over a longer period the LOEL of 16 mg/kg bw/d for tumour formation from an oral study was used but this was adjusted to 128 mg/kg bw/d for dermal exposure using the dermal absorption factor of 12.5%.

*Volume 2: Toxicology and OHS report* (pages 20–22) provides a detailed explanation for determination of the ADI, the ARfD and NOELs used for public health standards. A full justification for using carcinogenicity study in p53 'knockout' mice and supplementary studies on the mechanism of tumour formation is also given. The ADI value was increased from 0.003 to 0.008 mg/kg bw/d based on the assessment of a 6-month study in p53-deficient mice, which significantly increased the weight of evidence that carbaryl was not genotoxic *in vivo*, thereby reducing the potential effect on human health. This enabled the component for 'confidence that carbaryl is genotoxic' to be reduced from two to one. Using the National Health and Medical Research Council's criteria for deriving safety factors, the overall safety factor of 4000 was reduced to 2000. This was applied to the LOEL of 16 mg/kg bw/d for vascular tumours in male mice, giving the revised ADI value of 0.008 mg/kg bw/d. ADI values are set on the NOELs or LOELs but human epidemiological studies do not provide these values. Therefore, the most relevant animal studies are used for setting an ADI unless a human study is available giving a NOEL or LOEL.

This is consistent with international practice. In 2001 the JMPR established an ADI of 0.008 mg/kg bw on the basis of the LOAEL of 100 ppm, equal to 15 mg/kg bw per day. This was derived using a safety factor of 2000, which incorporated an extra safety factor of 20 in view of the occurrence of this rare and malignant type of tumour, for which a no-effect level could not be identified. The meeting concluded that the increased incidence of vascular tumours was likely to be species- and sex-specific but, in view of the rarity and malignancy of these tumours, they could not be discounted in human risk assessment.

## PROTECTIVE CLOTHING

Kendon noted that it was asserted that there are no options for protective clothing to safely prepare and hand use the 800 mg/kg WP products (PRF report, Volume 1, page 13, 2nd and 4th paragraphs). The values of penetration through gloves of 2% and through clothing of 5% (Volume 2, page 63) seem to be much higher than the measured spray application values (Volume 2, pages 55–62). For full chemical protective clothing these values would be expected to be lower, particularly for mixing and loading operations by professional users compared with application of dust to dogs by the non-professional (Volume 2, page 52). Kendon questioned whether the exposure modelling advised in the PRF report, Volume 2 on pages 63–81, was really applicable for professional users wearing appropriate chemical protective clothing, gloves and respiratory protection.

In the study by Merricks (1998), summarised in the PRF report, Volume 2, pages 59–62, inhalational and dermal exposures were measured in a group of human volunteers. The duration of the study was only 13 minutes (range 8–18 minutes). The data suggested that there was a tendency for the carbaryl levels on

inner dosimeters to correlate positively with those on the outer clothing, but the association was not consistent. There were many examples where a high deposition rate on the external clothing did not lead to extensive carbaryl residues on the inner dosimeter. Conversely, there were many examples where the inner dosimeter was more heavily contaminated than would be expected from carbaryl levels on the external clothing. Therefore, due to the limitations of this study (very short duration), it is preferable to use exposure modelling for estimating exposure to workers. The use of chemical protective clothing, gloves and respiratory protection has been reviewed again following these comments.

#### HANDLING AND DELIVERY OF 800 GM/KG WETTABLE PRODUCTS

Kendon questioned the technology regarding the supply of carbaryl WP formulations in WSP. They raised the issue of how the packaging could be made to work and not break down in storage. Kendon suggested that a better method would be measure packs that deliver the exact amount of product and also noted that there are new mixing tanks on current sprayers which have been designed to handle powders.

The OCS advised that new technology is very advanced and WSPs do not break down in storage. It is not possible to assess new model sprayers unless details of such equipment are submitted.

The method of delivery of product in measure packs and WSP is similar, although with WSP there is no requirement to open the pack and therefore there will be limited exposure to the user from the powder. The WSPs are added to a spray tank half-filled with water at the required concentration and the tank is then agitated. This allows the packaging to dissolve and the product to be released and mixed into the water as the remainder of the tank is filled. Measure packs, while delivering the exact amount of product, must be opened and mixed into a paste. This method results in higher exposure during the mixing process than does the WSP.

The APVMA advises that there are many products currently registered where the delivery method for WPs is WSP.

#### HAND-HELD APPLICATIONS

Kendon noted that the concentration of the WP and SC once made is the same, depending on the target species, and questioned the difference in recommendations. The Merricks data (PRF report, Volume 2, pages 52 and 55) do not appear relevant to the professional application of carbaryl. The assessment needs to be reconsidered to take into account professional users with enclosed mixing tanks using chemical protective clothing, gloves and respirator protection with appropriate lowered estimated transmission/penetration figures.

The OCS noted the comment that the Merricks data (PRF report, Volume 2, pages 52 and 55) do not appear relevant to the professional application of carbaryl. The data are indeed relevant for professional users but the recommendations were reviewed again for hand-held applications. It is agreed that once the spray is made, exposure will be the same for both WP and SC formulations. For knapsack-spraying application, the risk is acceptable but not for low-pressure hand wand. If the mixer/loader exposure to WP products is

eliminated by using WSP, the risk will be acceptable. Therefore, if WP is used in WSP, then hand-held applications can be carried out using WP formulations.

#### COMMENT ON THE PRELIMINARY REVIEW FINDINGS REPORT, VOLUME 1, PAGE 13, 1ST PARAGRAPH

Kendon commented that some of the wording in the PRF report, Volume 1, page 13, 1st paragraph, was confusing and leaves the reader with the view there is a real problem that needs to be addressed, even though the actual data for humans do not support the view that there is a problem. Kendon commented that the word 'mice' should read 'in genetically sensitive male mice' because, as expressed, it implies 'all mice'. The word 'unlikely' leaves the formation of vascular system tumours as 'likely' at normal exposure levels. The term 'epidemiology studies' should be changed to 'actual epidemiology studies', to give weight to real studies on humans that did not produce an association with cancer development.

The OCS commented that the effects occurred in mice and they were not genetically sensitive. The use of the word 'unlikely' has been amended as it is not very clear. Regarding the use of 'actual epidemiology studies', there is no need to say 'actual' as all epidemiological studies are actual. The sentence does highlight that the studies were conducted in farmers and production workers.

#### COMMENT ON THE PRELIMINARY REVIEW FINDINGS REPORT, VOLUME 2, PAGE 64

Kendon commented that the comment by the OCS in the PRF report, Volume 2, page 64 that the OCS has evaluated the extrapolation from non-professional users to professional users appears to be guesswork.

The OCS advised that the word 'evaluated' has been changed in the amended report.

### 3.6 Protected data

At the start of the review, registrants were required under s.32 of the Agvet Code to provide data and information to the APVMA that are relevant to the reconsideration. The Agvet Codes provide that a person who authorised the use of protected information by the APVMA in conducting the review of the continued approvals or the registration of a product of another party may be eligible to receive compensation from that other party. Protected information remains protected for a period of time determined by the regulations to the Agvet Codes. The APVMA must not use protected information to support the approval (or the continued approval) of another, active constituent for a proposed or existing chemical product or registration (or the continued registration) of another chemical product, unless the two parties have agreed to the terms of compensation to be paid by the registrant of that other chemical product to the owner of the protected information. There are currently no data that were relied on for the reconsideration with a period of protection that had not expired at the time the review was finalised.

## 4 REVIEW OUTCOMES AND REGULATORY DECISIONS

On the basis of the evaluation of the submitted data and information (including protected information), the following regulatory actions have been taken regarding the continued registrations and approvals of carbaryl for agricultural uses in Australia.

### 4.1 Vary conditions of label approval

#### Changes to labels

As an outcome of the review, the following changes have been made to the approved labels.

#### *Deletion of use patterns*

The following uses have been deleted from approved labels:

- (a) Use on berry fruits (except raspberries and strawberry commercial runners)
- (b) Use on fruit general
- (c) Uses on citrus (except oranges and lemons)
- (d) Use on cherries
- (e) Use on kiwifruit
- (f) Use on grapes (except butt treatment)
- (g) Use on sunflower and linseed crops
- (h) Use on vegetable crops (except potatoes, sweet potato, beetroot and turnip (swede), and limited uses on cucurbits)
- (i) Use on sweet corn
- (j) Use on stored cereal grains
- (k) Use by high-volume powered hand-held application to garden beds, compost heaps, treatment around buildings (except for the eradication of insect nests).

#### *Variation to use patterns*

The following variations have been made to the product labels:

- (a) Feijoa, guavas—only to be used on non-flowering/non-fruiting trees
- (b) Grapes—for cutworms when applied around base of vine
- (c) Jaboticaba, jackfruit—only to be used on non-flowering/non-fruiting trees
- (d) Loquats—only to be used for fruit thinning, up to fruit size 10 mm
- (e) Litchis—only to be used on non-flowering/non-fruiting trees
- (f) Rambutans—only to be used on non-flowering/non-fruiting trees
- (g) Raspberries—the WHP has been increased to 7 days
- (h) Cucurbits—only to be used for melons and other flowering cucurbits, up to time of flowering
- (i) Strawberries—only to be used in commercial runner production.

### ***Restrictions***

The following restriction statements have been added to the labels:

**DO NOT** make more than four applications per season to avocados.

**DO NOT** make more than three applications per season to mangoes.

### ***Livestock feeding restrictions***

#### **Cotton**

The following livestock feeding restrictions have been included on all product labels where appropriate:

This product must not be used on cotton where cotton trash, fodder or stubble (excluding seed and hulls) will or may be fed to livestock.

**DO NOT** feed cotton fodder, stubble or trash to livestock

### ***Withholding periods***

As an outcome of the review the following WHPs have been set and added to labels.

#### **Cereal grains**

**DO NOT** harvest for 14 days after application

**DO NOT** graze or cut for stock food for 14 days after application

Cereal grain treated with 16 ml of this preparation must be held in storage and not be used for processing for human consumption or for stock food within 90 days of treatment.

**Pasture and Lucerne**

**DO NOT** graze or cut for stock food for 7 days after application

**Cotton**

**DO NOT** harvest for 3 days after application

**Oranges, lemons, beetroot, potatoes, sweet potato, turnips (swede)**

**DO NOT** harvest for 3 days after application

**Stone fruit (except cherries)**

**DO NOT HARVEST** for 5 weeks after application

**Pome fruit**

**DO NOT HARVEST** for 11 weeks after application

**Avocados**

**DO NOT HARVEST** for 3 days after application

**Mangoes and raspberries**

**DO NOT HARVEST** for 7 days after application

**Cucurbits (flowering)**

Withholding period not required when used as directed (applied up to the time of flowering only)

**Macadamia nuts, pecan nuts**

Withholding period not required when used as directed

**Grapes**

Withholding period not required when used as directed (for stem treatment for cutworms only)

### **Strawberries**

Withholding period not required when used as directed (for use in commercial runner production only)

### **Feijoa, guavas, jaboticaba, jackfruit, litchis, rambutans**

Withholding period not required when used as directed (use only when tree not flowering or not bearing fruit)

### **Loquats**

Withholding period not required when used as directed (use for fruit thinning, up to fruit size 10 mm)

### ***Re-entry periods***

As a result of the occupational health and safety assessment, the following re-entry period statements have been added to labels.

#### **Raspberries and ornamental plants**

Do not allow entry into treated areas or re-handle treated plants for 8 days after treatment. When prior entry is required wear rubber gloves and cotton overalls buttoned to the neck and wrist. Clothing and gloves must be washed after each day's use.

#### **Nursery plants (tree crops in containers)**

Do not allow entry into treated areas or re-handle treated plants for 24 hours after treatment. When prior entry or re-handling is required wear rubber gloves and cotton overalls buttoned to the neck and wrist. Clothing and gloves must be washed after each day's use.

#### **Cotton crop**

Do not allow entry into treated areas for 2 days after treatment. When prior entry is required wear rubber gloves and cotton overalls buttoned to the neck and wrist. Clothing and gloves must be washed after each day's use.

#### **All other crops**

Do not allow entry into treated areas for 1 day after treatment. When prior entry is required wear rubber gloves and cotton overalls buttoned to the neck and wrist. Clothing and gloves must be washed after each day's use.

### *Changes to registered products for use on pigs*

One carbaryl product (Nufarm Flowable Carbaryl 500 Insecticide) was registered for use on pigs. From the data submitted it was determined that residues in pig tissues following treatment at the Australian label rate (0.5% solution) at 7-day WHP would comply with the mammalian tissue MRL. Therefore the APVMA is satisfied that the use of the registered carbaryl product on pigs in accordance with the instructions for use would not contain residues that are harmful to human beings.

This product was not registered at the time of finalisation of this review. If the product were to be reinstated, the label must be varied so that the veterinary use pattern for pigs is placed in a separate table on the label in order to distinguish it from the registered agricultural uses of the product. The following label statement may remain on the label:

**DO NOT** use less than 7 days before slaughter for human consumption.

### *Carbaryl WP formulation*

One WP formulation 800 g/L product (Kendon Carbaryl Wettable Powder Insecticide) was included in the review. Based on the potential for unacceptable levels of operator exposure, and because of insufficient information available to predict the extent of operator exposure, the delivery method for WP formulations of carbaryl must be changed. WP products are now required to be manufactured in measured WSP. This prevents user exposure as the packets are added directly into the spray tank, without needing to be opened.

### *Application methods for WP and SC products*

#### CHANGES TO MIXING/LOADING

Use of closed transfer/mixing systems for preparation of carbaryl SC products is required to reduce operator exposure to acceptable levels when mixing and loading products for aerial application. WP formulations are required to be provided in WSP. Closed transfer/mixing systems would therefore not be required for airblast and groundboom application of WP formulations supplied in measured packs of WSP.

#### CHANGES TO CURRENT APPLICATION METHODS

If the product is being applied by air and flaggers are required, they must be protected by engineering controls. Engineering controls include closed cabins of tractors or vehicles where a flagger will not be exposed to spray from the aircraft.

#### DELETION OF CURRENT APPLICATION METHODS

The application of carbaryl in pest control activities in domestic, commercial and industrial settings involving use of powered hand-held spray equipment (other than the low-volume knapsacks) has been removed from labels, except for the eradication of insect nests.

**APPLICATION METHODS REQUIRING NO CHANGES**

Application by orchard airblast and groundboom spray can continue without change.

Application of WP (only if packed in WSP) and SC products by hand-held spray equipment to trees, ornamental plants, pigs and grain storage infrastructure can continue without change.

**Other label changes**

Arising from the assessment of data submitted to the review of carbaryl, and consideration of the expanded toxicological database on carbaryl, the OCS has made changes to public health standards; labels are required to be varied to comply with the new standards. Further details of the public health standards are provided in Chapter 5.

**Summary of review outcomes for continuation of uses**

A summary of the changes detailed above for each label use is provided in tables 9–14.

**Table 9: Tree and vine crops**

CROP	PESTS	ACTION TAKEN
Avocados	Red-shouldered leaf beetle  Monolepta beetle (NSW + QLD)	<b>Retain use</b>
Citrus	Bronze orange bug, citrus leaf-eating caterpillar, Fuller's rose weevil, fruit-piercing moth, light brown apple moth, orange fruit borer, pink wax scale, spined citrus bug, white wax scale, yellow peach moth	<b>Retain use</b> for oranges and lemons only
Feijoa, guavas	Orange fruit borer	<b>Retain use</b> on non-flowering/non-fruiting trees only
Fruit—general	Wingless grasshopper	<b>Delete from labels (move to specific fruit crops)</b>
Grapes	Grapeleaf blister mite, grapevine hawk moth, grapevine moth, light brown apple moth, cutworms, mealybugs, scale	<b>Retain use</b> for cutworms when applied around base of vine  <b>Delete other applications</b>
Jaboticaba, jackfruit	Swarming leaf beetle	<b>Retain use</b> on non-flowering/non-fruiting trees only
Kiwifruit	Light brown apple moth	<b>Delete from labels</b>
Loquats	Light brown apple moth	<b>Retain use</b> for fruit thinning, up to fruit size 10 mm

CROP	PESTS	ACTION TAKEN
Litchis	Caster oil looper, leaf-eating looper, macadamia nutborer, red-shouldered leaf beetle, swarming leaf beetle	<b>Retain use</b> on non-flowering/non-fruiting trees only
Macadamias	Macadamia nutborer, macadamia twig-girdler, red-shouldered leaf beetle, cornelian (butterfly), macadamia cup moth, macadamia nut moth, yellow peach moth	<b>Retain all uses</b>
Mangoes	Fig leafhoppers, pink wax scale, flattids	<b>Retain use</b>
Pecans	Orange fruitborer, yellow peach moth	<b>Retain all uses</b>
Pome fruit: apples, pears	Early fruit caterpillars, codling moth, light brown apple moth, pear leaf blister mite, pear and cherry slug, fruit thinning	<b>Retain all uses (WHP 77 days)</b>
Rambutans	Caster oil looper, red-shouldered leaf beetle, swarming leaf beetle	<b>Retain use</b> on non-flowering/non-fruiting trees only
Stone fruit: apricots, nectarines, peaches, plums, prunes	Green treehopper, light brown apple moth, oriental fruit moth, pear and cherry slug, red-shouldered leaf beetle, orange fruit borer, <i>Heliothis</i> (budworms), European earwig	<b>Retain all uses</b> (except cherries) <b>Delete cherries from labels</b>

Table 10: Fruit and vegetables

CROP	PEST	ACTION TAKEN
Beans	<i>Heliothis</i> (budworms), pumpkin beetle, 28-spotted ladybird	<b>Delete from labels</b>
Blueberries	Grasshoppers	<b>Delete from labels</b>
Cape gooseberry	Threelined potato beetle	<b>Delete from labels</b>
Capsicum	Beetles, weevils	<b>Delete from labels</b>
Carrots	Vegetable weevil	<b>Delete from labels</b>
Cucurbits	Cucurbit stemborer, <i>Heliothis</i> (budworms), pumpkin beetle, 28-spotted ladybird	<b>Retain use</b> for melons and other flowering cucurbits, up to time of flowering only
Leafy vegetables	Vegetable weevil, brown vegetable weevil	<b>Delete from labels</b>
Potatoes	Potato moth	<b>Retain use</b>
Sweet potato	Sweet potato weevil	<b>Retain use</b>
Raspberries	Grasshoppers, light brown apple moth, raspberry fruit caterpillar	<b>Retain all uses with 7 day WHP</b>

CROP	PEST	ACTION TAKEN
Root vegetables	Vegetable weevil, brown vegetable weevil	<b>Retain uses</b> for beetroot, turnips (swede)
Strawberry	Grasshoppers	<b>Retain use</b> for commercial runner production only
Tomatoes	Leafminer caterpillars, tomato leaf miner, false wireworm	<b>Delete from labels</b>
Vegetables—general	Potato moth, European earwig, cabbage white butterfly, cabbage moth, Rutherglen bug, pumpkin beetle, 28-spotted (leaf-eating) ladybird, cutworms, green vegetable weevil, vegetable bug; wingless grasshoppers	<b>Delete from labels. Replace with specific entries for permitted crops</b>

Table 11: Field crops and pastures

CROP	PEST	ACTION TAKEN
Cereal grain storage up to 3 months (except malting barley)	Lesser grain borer	<b>Delete use</b>
Cereal, grain storage from 3 months up to 9 months. Grain stores (surface spraying)		<b>Delete use</b>
Disinfection of grain storage buildings		<b>Retain use</b>
Cereals (general) pre-harvest uses only	Rutherglen bug, <i>Heliothis</i> spp, armyworms, cutworms, Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	<b>Retain all uses</b>
Cotton	Rough bollworm	<b>Retain all uses</b>
Duboisia	Australian plague locust, cluster caterpillar, grasshoppers, leaf-eating ladybirds, sandal-box hawk moth	<b>Retain all uses</b>
Kenaf	Red-shouldered leaf beetle	<b>Retain all uses for non-food crops</b>
Linseed	<i>Heliothis</i> (budworms)	<b>Delete from labels</b>
Lucerne	<i>Heliothis</i> (budworms), leafhoppers (jassids), leaf roller, lucerne flea, sitona weevil	<b>Retain all uses</b>
Maize	Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	<b>Retain all uses</b>
Pastures, pasture	Lucerne leafroller, grass caterpillar, pasture cockchafer, army worm, <i>Heliothis</i> (budworms), pasture leafhopper,	<b>Retain all uses</b>

CROP	PEST	ACTION TAKEN
seed crops	sitona weevil, cutworms, yellow-winged locust, migratory locust, Australian plague locust	
Rice	Brown planthopper	<b>Retain all uses</b>
Rosella	Leaf-eating beetles	<b>Retain all uses for non-food crops</b>
Sorghum	Sorghum midge, Rutherglen bug, <i>Heliothis</i> spp, armyworms, cutworms, Australian plague locust, wingless grasshopper, yellow-winged locust, migratory locust	<b>Retain all uses</b>
Sunflower	Black sunflower scarab, sorghum midge, Rutherglen bug, <i>Heliothis</i> spp, armyworms, cutworms, wingless grasshopper	<b>Delete from labels</b>
Sweet corn	Red-shouldered leaf beetle	<b>Delete from labels</b>

Table 12: Animal treatment

ANIMAL	PEST	ACTION TAKEN
Horses and ponies	Sucking louse, body louse, hard ticks, bush tick, mites, ear mites, leg mange	<b>Retain all uses</b>
Horses and dogs	Mange, girth itch, Queensland itch, lice	<b>Retain all uses</b>
Pigs	Body louse, sarcoptic mange	<b>Not applicable. Product no longer available</b>

Table 13: Ornamentals

SITUATION	PEST	ACTION TAKEN
Elm trees	Elm leaf beetle	<b>Retain all uses</b>
Ornamentals	Tobacco leaf miner, potato moth, earwig, cabbage moth, cabbage white butterfly, Rutherglen bug, green vegetable bug, leaf-eating ladybird, <i>Heliothis</i> spp, pumpkin beetle, cutworms, wingless grasshopper, beetles, caterpillars, chewing insects, sucking insects, leafroller moth, looper, white wax scale	<b>Retain all uses</b>
Roses	Cluster caterpillar, light brown apple moth	<b>Retain all uses</b>

Table 14: Miscellaneous uses

SITUATION	PEST	ACTION TAKEN
Concealed or underground nests in and around home garden, shed	Vespid wasp (English/European wasps), honey bees in concealed hives	<b>Retain all uses</b>
Garden beds, compost heaps, treatment around buildings	Black Portuguese millipede	<b>Retain all uses</b> for WP product packed in WSP
Tobacco bulk sheds	Tobacco beetles, ants, fleas, moths, weevils	<b>Retain all uses</b>
Commercial and industrial areas	Ants, fleas, moths, weevils	<b>Delete uses</b>
	Vespid wasp (English/European wasps), honey bees	<b>Delete uses except eradication of insect nests</b>
	European earwig	<b>Retain use</b> Low-volume knapsack application acceptable
Non-crop, commercial and industrial areas, rights of way	Plague grasshopper, plague locust, wingless grasshopper	<b>Retain all uses</b> (ground boom application)
	Ants, fleas and weevils	<b>Delete from labels</b> High-volume powered hand-held application unacceptable
	European earwig	<b>Retain use</b> Restrict to low-volume knapsack application

### Label variations

The APVMA was NOT SATISFIED that labels for products in Table 15 contained adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes, as well as those referred to in regulations 11 and 12 of the Agvet Code Regulations. Product labels also contained uses patterns that was no longer acceptable by the APVMA. However, the APVMA was SATISFIED that the conditions of label approval could be VARIED, in accordance with s.34(5) of the Agvet Codes.

The APVMA was SATISFIED that varied labels would contain adequate instructions. On this basis the APVMA was SATISFIED that continued registration of the product in accordance with its instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling
- would not be likely to have an effect that is harmful to human beings
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

## 4.2 Affirm product registration and label approval

Section 4.1 identifies various changes to labels as an outcome of the review. These variations to label instructions would satisfy the requirements for continued registration of products identified in Table 15. The APVMA has affirmed the product registrations as the label variations have been completed.

**Table 15: Registered products and label approval numbers after recommended variations in accordance with the proposed label changes described in Section 4.1**

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	AFFIRMED LABEL APPROVAL NUMBERS AFFIRMED
40143	Joseph Lyddy G-Wizz Insecticidal Dry Shampoo For Horses And Ponies	Waproo Pty Ltd	40143/0607
40145	Joseph Lyddy Y-Itch Animal Insecticide Bactericide	Waproo Pty Ltd	40145/50837
40146	Bugmaster Flowable Insecticide	Tessengerlo Kerley, Inc.	40146/56719
52213	David Grays Carbaryl 500 Flowable Insecticide	David Gray & Co. Pty Ltd	52213/56745

## 4.3 Cancellation of all but the most recently approved label

The APVMA was NOT SATISFIED that previously-approved product labels for currently registered products listed in Table 16 contained adequate instructions in relation to the criteria set out in s.14(3)(g) of the Agvet Codes as well as those referred to in regulations 11 and 12 of the Agvet Code Regulations and contain uses patterns that have been deleted. On this basis, previously approved labels were cancelled.

**Table 16: The following label approvals are deemed not to contain adequate instructions and have been cancelled**

PRODUCT NUMBER	LABEL APPROVAL NUMBERS CANCELLED	
40143	40143/0500	
40145	Ψ	
40146	40146/01 40146/02 40146/0500 40146/0410	40146/1197 40146/4535 40146/0603
52213	52213/0100	52213/47047

Ψ Label transitioned from the states does not have an approval number.

## 4.4 Cancellation as a consequence of review findings

The product listed in Table 17 below has not been varied to meet the requirements of the APVMA. This product has not had WSP approved to meet the OHS requirements identified as part of the review.

On this basis the APVMA was NOT SATISFIED that continued registration of this product in accordance with its instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling
- would not be likely to have an effect that is harmful to human beings
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

Therefore, the APVMA proposes that, consistent with the outcomes of the review, the registration and approvals for this product be cancelled. This product has been cancelled.

**Table 17: Registered products and label approval numbers cancelled as a consequence of the review findings**

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBER
49326	Kendon Carbaryl Wettable Powder Insecticide	Kendon Chemicals & Manufacturing Co. Pty Ltd	49326/1098 49326/0400

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## 4.5 Withdrawn carbaryl products

A number of carbaryl products (Table 18) were voluntarily withdrawn or not reregistered since the review began. Once cancellation of registration was formally effected, reconsideration of these products was no longer required.

**Table 18: Carbaryl products included in the review that were withdrawn before the review was completed**

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
31994	Agchem Carbaryl 800 WP Insecticide	Crop Care Australasia Pty Ltd	Ψ
31996	Chemspray Carbaryl 80 Insecticide	Nuturf Pty Ltd	Ψ
32005	ICI Septene Liquid Insecticide	Crop Care Australasia Pty Ltd	Ψ
32017	Sevin 500 Carbaryl Flowable Insecticide	Bayer CropScience Pty Ltd	Ψ
32020	Bugmaster 800 Insecticide	Bayer CropScience Pty Ltd	Ψ
32022	Top Carbaryl Chewing Insect Spray	Pivot Ltd	Ψ
32092	Nufarm Fenitrocarb Grain Protectant Powder Insecticide	Nufarm Australia Ltd	Ψ
39248	Agchem Carbaryl 500 Insecticide	Crop Care Australasia Pty Ltd	Ψ
41093	Barmac Carbene Liquid Insecticide	Barmac Industries Pty Ltd	Ψ
46834	Chipco Bugmaster Insecticide	Bayer CropScience Pty Ltd	Ψ
48150	Crop Care Carbaryl 800 WP Insecticide	Crop Care Australasia Pty Ltd	48150/02
32009	Nufarm Flowable Carbaryl 500 Insecticide	Nufarm Australia Ltd	32009/0603 32009/0902 32009/0801 32009/0300

Ψ Labels transitioned from the states do not have an approval number.

## 5 AMENDMENTS TO STANDARDS

### 5.1 Public health standards

Arising from the OCS's assessment of data submitted to the review of carbaryl and consideration of the toxicological database the following advice was provided by the OCS.

#### Acceptable Daily Intake

At the start of the review, the ADI for carbaryl was 0.004 mg/kg bw/d, derived by applying a 4000-fold safety factor to a LOEL of 100 ppm (16 mg/kg bw/d) for vascular tumours occurring in male mice in a 2-year dietary study. The review recommended that the ADI be revised to 0.008 mg/kg bw/d, derived by applying a 2000-fold safety factor to the same LOEL of 100 ppm for vascular tumour formation. Further details can be found under 'Acceptable Daily Intake' in Section 1.4 in *Volume 2: Toxicology and OHS report*.

#### Acute Reference Dose

Arising from the assessment of the data submitted to the review, the OCS set an ARfD of 0.01 mg/kg bw, by applying a 100-fold safety factor to a NOEL of 1 mg/kg bw/d, established in rat 13-week subchronic and developmental neurotoxicity studies. The NOEL was based on behavioural indications of autonomic neurotoxicity and brain, plasma and erythrocyte ChE depression (LOEL=10 mg/kg bw/d). Further details can be found under 'Acute Reference Dose' in Section 1.4 in *Volume 2: Toxicology and OHS report*.

#### Health Value for Australian drinking water

The existing Health Value for carbaryl of 0.03 mg/L in drinking water remains unchanged.

#### Poisons schedule

Carbaryl is classified as a Schedule 6 poison in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with Schedule 5 entries for preparations containing 10 per cent or less of carbaryl (except when included in Schedule 4), or when impregnated into plastic resin material containing 20 per cent or less of carbaryl. Carbaryl preparations for human therapeutic use are listed in Schedule 4, but none are currently on the Australian market.

#### First Aid Instructions

No changes were recommended to the current First Aid Instructions for carbaryl.

The following standard statements for carbaryl (Table 19) were specified in the FAISD Handbook, 31 December 2009, [www.health.gov.au/internet/main/publishing.nsf/Content/ocs-faisd-handbook.htm](http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-faisd-handbook.htm). These

instructions were considered appropriate for a carbamate pesticide of moderate acute toxicity, and no revisions were proposed.

**Table 19: Current First Aid Instructions for carbaryl**

CONCENTRATION	CODE	FIRST AID INSTRUCTION
More than 12 per cent	m	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre Phone Australia 131 126; New Zealand 0800 764 766 or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.
12 per cent or less	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126; New Zealand 03 474 7000

## Safety Directions and personal protective equipment

No changes were recommended to the current Safety Directions for carbaryl SC, lotion or bar products.

The following safety directions for carbaryl (Table 20) are currently specified in the FAISD Handbook, 31 December 2011, [www.health.gov.au/internet/main/publishing.nsf/Content/ocs-faisd-handbook.htm](http://www.health.gov.au/internet/main/publishing.nsf/Content/ocs-faisd-handbook.htm).

**Table 20: Safety Directions for carbaryl products**

FORMULATION	SAFETY DIRECTIONS	STATEMENT
SC 500 g/L or less	120 130 131 133	Product is poisonous if absorbed by skin contact or swallowed.
	161 162 164	Will irritate the eyes and skin.
	210 211	Avoid contact with eyes and skin.
	279 280 281 282 290 292a 294	When opening the container, preparing spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow-length PVC gloves.
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360 361 366	After each day's use, wash gloves and contaminated clothing.
Lotion 2 g/L or less with sulfur 20 g/L or less and zinc oxide 50 g/L or less	120, 130, 131, 133	Product is poisonous if absorbed by skin contact or swallowed.
	160, 162, 163, 164	May irritate the eyes, nose and throat and skin.
	180	Repeated exposure may cause allergic disorders.
	210, 211	Avoid contact with eyes and skin.

FORMULATION	SAFETY DIRECTIONS	STATEMENT
	220, 222	Do not inhale vapour.
	272	Ensure adequate ventilation during use.
	279, 280, 283, 290, 295	When opening the container and using the product wear elbow-length neoprene, nitrile or butyl rubber gloves.
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360, 361	After each day's use, wash gloves.
BAR 40 g/kg or less	120, 130, 131, 132, 133	Product is poisonous if absorbed by skin contact, inhaled or swallowed.
	160, 162, 164	May irritate the eyes and skin.
	210, 211	Avoid contact with eyes and skin.
	220, 221	Do not inhale dust.
	279, 283, 290, 292b, 312	When using the product wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and rubber gloves.
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360, 361	After each day's use, wash gloves.

Current Safety Directions for WP carbaryl products are included in Table 21 below. These Safety Directions will be deleted at the completion of the review because no WP and LD products are currently registered and new Safety Directions for SC products have been established as discussed above.

**Table 21: Pre-review Safety Directions for carbaryl WP products**

FORMULATION	SAFETY DIRECTIONS	STATEMENT
WP LD SC all strengths	120, 130, 131, 133	Product is poisonous if absorbed by skin contact or swallowed.
	210, 211	Avoid contact with eyes and skin.
	220, 221, 223	Do not inhale dust/spray mist.
	279, 281, 290, 294,	When preparing the product wear elbow-length PVC gloves.
	340, 342	If product on skin, immediately wash area with soap and water
	350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
	360, 361	After each day's use, wash gloves.

## Warning Statements

Any product that may be applied on and around the exterior of domestic premises: The label should bear an additional warning statement: 'Avoid bare skin contact with treated surfaces'.

## 5.2 Maximum Residue Limits Standard

Recommendations for variation to MRLs have been made throughout the review. Some of those recommendations were implemented before the review was finalised. The MRL Standard can be found on the APVMA website: [www.apvma.gov.au/residues/standard.php](http://www.apvma.gov.au/residues/standard.php).

The following changes are recommended to Table 1 of the MRL Standard.

Table 1 of the MRL Standard

COMPOUND	FOOD	MRL (mg/kg)	
		AT START OF REVIEW	ON FINALISATION
<b>Carbaryl</b>			
<b>VARIATIONS TO TABLE 1 ENTRIES</b>			
FS 0240	Apricot	10	DELETE
VS 0621	Asparagus	10	DELETE
FI 0326	Avocado	10	2
FI 0327	Banana [in the pulp]	5	DELETE
FB 0264	Blackberries	10	DELETE
FB 0020	Blueberries	7	DELETE
FT 0289	Carambola	5	DELETE
GC 0080	Cereal grains	T5	DELETE <sup>a</sup>
FS 0013	Cherries	5	DELETE
FC 0001	Citrus fruits	7	DELETE
SO 0691	Cotton seed	1	3
FI 0332	Custard apple	5	DELETE <sup>a</sup>
FB 0266	Dewberries (including Boysenberry and Loganberry)	10	DELETE
MO 0105	Edible offal (mammalian)	T0.2	3
PE 0112	Eggs	T0.2	*0.02
FI 0371	Elephant apple	5	DELETE
FI 0335	Feijoa	5	*0.01
VC 0045	Fruiting vegetables, Cucurbits	3	*0.01
HS 0783	Galangal, rhizomes [fresh]	T5	DELETE

COMPOUND	FOOD	MRL (mg/kg)	
		AT START OF REVIEW	ON FINALISATION
FI 0351	Granadilla	5	DELETE
FB 0269	Grapes	5	*0.01
FT 0298	Grumichama [Brazilian cherry]	5	DELETE
FT 0336	Guava	5	*0.01
FT 0300	Jaboticaba	5	*0.01
FI 0338	Jackfruit	5	*0.01
	Jambu	5	DELETE
FI 0341	Kiwifruit	10	DELETE
VL 0053	Leafy vegetables	10	DELETE
FI 0343	Litchi	5	*0.01
FI 0342	Longan	5	*0.01
FI 0345	Mango	5	2
MM 0095	Meat [mammalian]	T0.2	0.07
ML 0106	Milks	T*0.05	0.1
FS 0245	Nectarine	10	DELETE
VO 0442	Okra	10	DELETE
FT 0305	Olives	10	DELETE
DM 0305	Olives, processed	1	DELETE
FI 0350	Papaya [pawpaw]	5	DELETE
FI 0351	Passion fruit	5	DELETE
FS 0247	Peach	10	DELETE
FS 0014	Plums (including Prunes)	5	DELETE
FP 0009	Pome fruits	5	0.2
VR 0589	Potato	0.2	0.1
PO 0111	Poultry, Edible offal of	T5	0.2
PM 0110	Poultry meat	T0.5	*0.02
FI 0358	Rambutan	5	*0.01
FB 0272	Raspberries	10	DELETE
FI 0359	Sapodilla	5	DELETE
FI 0360	Sapote, Black	5	DELETE
FI 0361	Sapote, Green	5	DELETE
FI 0362	Sapote, Mammey	5	DELETE
FI 0363	Sapote, White [casimiroa]	5	DELETE
FB 0275	Strawberry	7	*0.01
GS 0659	Sugar cane	T*0.05	DELETE
SO 0702	Sunflower seed	1	DELETE

COMPOUND	FOOD	MRL (mg/kg)	
		AT START OF REVIEW	ON FINALISATION
VO 0447	Sweet corn (corn-on-the-cob)	1	DELETE
TN 0085	Tree nuts	1	DELETE
TN 0085	Tree nuts [whole in shell]	10	DELETE
HS 0794	Turmeric, root [fresh]	T5	DELETE
	Vegetables [except asparagus; fruiting vegetables, cucurbits; leafy vegetables; okra; potato; sweet corn (corn-on-the-cob)]	5	DELETE
CM 0654	Wheat bran, unprocessed	T20	10
GC 0640	Barley	ADD	15 <sup>a</sup>
VR 0574	Beetroot	ADD	0.5
GC 0080	Cereal grains [except Barley, Rice and Sorghum]	ADD	5 <sup>ab</sup>
TN 0665	Coconut	ADD	*0.01
FC 0204	Lemon	ADD	3
TN 0669	Macadamia nut	ADD	2
SO 0088	Oilseed [except Cotton seed]	ADD	0.1
FC 0004	Oranges, Sweet, Sour	ADD	3
TN 0672	Pecan	ADD	2
VD 0070	Pulses	ADD	0.1
FB 0272	Raspberries, Red, Black	ADD	15
GC 0649	Rice	ADD	7
GC 0651	Sorghum	ADD	10 <sup>a</sup>
FS 0012	Stone fruits [except cherry]	ADD	0.5
VR 0497	Swede	ADD	2
VR 0508	Sweet potato	ADD	0.1
VR 0506	Turnip, Garden	ADD	2

(\*) denotes that the MRL has been set 'at or about' the limit of analytical quantitation.

<sup>a</sup> Varied by amendment No. 6N to the APVMA MRL Standard, 7 December 2010.

<sup>b</sup> Exception for rice to be added on review finalisation

The following changes are recommended to Table 3 of the MRL Standard.

Table 3 of the MRL Standard

COMPOUND	RESIDUE
<b>DELETE</b>	
<b>Carbaryl</b>	Carbaryl
<b>ADD</b>	
<b>Carbaryl</b>	Commodities of plant origin: Carbaryl Commodities of animal origin: Sum of carbaryl and conjugates, hydrolysed to carbaryl, expressed as carbaryl

The following changes except for rice hulls have been made to Table 4 of the MRL Standard.

Table 4 of the MRL Standard

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)	
<b>Carbaryl</b>			
<b>DELETE</b>	AF 0080	Forage of cereal grains	T100 <sup>a</sup>
	AS 0081	Straw and fodder (dry) of cereal grains	T100 <sup>a</sup>
<b>ADD</b>	AF 0080	Forage of cereal grains	100 <sup>a</sup>
		Grass pastures	400 <sup>a</sup>
	AS 0162	Hay or fodder (dry) of grasses	300 <sup>a</sup>
		Legume forage	400 <sup>a</sup>
		Legume fodder	100 <sup>a</sup>
	AM 0165	Miscellaneous fodder and forage crops	300 <sup>a</sup>
		Sorghum bran	20 <sup>a</sup>
		Rice hulls	15
AS 0081	Straw and fodder (dry) of cereal grains	100 <sup>a</sup>	

<sup>a</sup> Varied by amendment No. 6N to the APVMA MRL Standard, 7 December 2010.

The following changes are recommended to Table 5 of the MRL Standard.

Table 5 of the MRL Standard

SUBSTANCE	USE
<b>ADD</b>	
<b>Carbaryl</b>	<ul style="list-style-type: none"><li>• As an insecticide in non-crop areas including commercial, industrial and domestic areas, tobacco storage sheds and rights of way</li><li>• As an insecticide on ornamentals and other non-food or animal feed crops and trees</li></ul>

## APPENDIX

List of products and associated label approvals considered as part of the reconsideration of carbaryl agricultural uses

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
40143	Joseph Lyddy G-Wizz Insecticidal Dry Shampoo For Horses And Ponies	Waproo Pty Ltd	40143/0500
40145	Joseph Lyddy Y-Itch Animal Insecticide Bactericide	Waproo Pty Ltd	Ψ
40146	Bugmaster Flowable Insecticide	Bayer CropScience Pty Ltd*	40146/01 40146/02 40146/0500 40146/1197 40146/4535 40146/0603
52213	David Grays Carbaryl 500 Flowable Insecticide	David Gray & Co. Pty Ltd	52213/0100
49326**	Kendon Carbaryl Wettable Powder Insecticide	Kendon Chemical & Manufacturing Co. Pty Ltd	49326/0400 49326/1098
32009**	Nufarm Flowable Carbaryl 500 Insecticide	Nufarm Australia Limited	32009/0603 32009/0902 32009/0801 32009/0300

Ψ Label transitioned from the states does not have an approval number.

\* The registration of the product was transferred to Tessenderlo Kerley, Inc. before the completion of the review.

\*\* Registrations of these products were voluntarily cancelled or discontinued before the completion of the review.