Australian Government

Australian Pesticides and Veterinary Medicines Authority

CARBARYL

Part 2: Uses of carbaryl in agricultural situations

VOLUME 3: RESIDUES TECHNICAL REPORT

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

JUNE 2012

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ACRONYMS, ABBREVIATIONS AND DEFINITIONS

ADI	The **Acceptable Daily Intake** 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 (mg/kg bw). 'Without appreciable risk' means that adverse effects will not result even after a lifetime of exposure.
ai	**Active ingredient**
APVMA	The **Australian Pesticides and Veterinary Medicines Authority** 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.
ARfD	The **Acute Reference Dose** 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.
bw	**Body weight**
Codex	The **FAO/WHO Codex Alimentarius Commission** 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.
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.
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.
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.
NRS	The **National Residue Survey** monitors residues of agricultural and veterinary chemicals and environmental contaminants in Australian food commodities. The NRS programs include random, targeted and compliance monitoring of agricultural and veterinary chemical residues and environmental contaminants in selected animal products (meat, egg, honey and fish) and plant products (grain, oilseed and horticulture).
OCS formerly OCSEH	The **Office of Chemical Safety** is part of the Office of Health Protection in the Australian Government Department of Health and Ageing. It is responsible for human health risk 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.
PHI	The **Pre-harvest Interval** is the interval between treatment and harvest in residues studies.
ppm	**Parts per million** 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.
PRF	A **Preliminary Review Findings Report** 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.
STMR	**Supervised Trials Median Residue**
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.

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1 RESIDUES ASSESSMENT

1.1 Introduction

The review of carbaryl was initiated in 1995, as it was considered that the Australian Pesticides and Veterinary Medicines Authority (APVMA) did not hold sufficient residue data to support the use of carbaryl in cereals, either by field application or for use on stored grain. The scope of the review for carbaryl initially included the reconsideration of residue data and maximum residue limits (MRLs) related to cereal grains and animals that may be fed on treated cereal products. The scope of the review was later extended to include home garden and home veterinary products, to consider whether the uses of these products would have an effect that was harmful to human beings (National Registration Authority Gazette no. 7, 6 July 1999).

In 2001 the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) set an Acute Reference Dose (ARfD) for carbaryl, and the Office of Chemical Safety (OCS) in the Department of Health and Ageing recommended an ARfD in December 2002. As a consequence of the establishment of the ARfD by the OCS, the scope of the carbaryl review was again broadened so that the APVMA could assess the dietary risk of carbaryl (APVMA Gazette no. 6, 3 June 2003).

The initial residues assessment report was published in July 2006 for public consultation in conjunction with the Preliminary Review Findings (PRF) report. Following the public consultation period the residues assessment considered additional data submitted for avocados and mangoes. Additionally, industry submissions regarding proposed longer withholding periods (WHPs) for certain tropical fruits, grapes, cucurbits, pome fruit and stone fruit were considered and the use of carbaryl on oranges and lemons was reassessed in light of further information about industry practices.

This assessment includes a revised dietary exposure assessment based on Food Standards Australia New Zealand's (FSANZ) 2009 revision of Australian dietary consumption figures. This revision has led to the recommendation that use on raspberries is not acceptable unless the WHP is extended to 7 days and that use on cereal grains post-harvest is not acceptable owing to acute exposure concerns for children.

This residues assessment report should be read in conjuction with the initial residues assessment report published in 2006. Only changes to the previous report are discussed in detail in this report.

1.2 Maximum residue limits

The Australian MRLs for carbaryl at the start of this review are tabulated in the previous report. Most of the pre-review Australian MRLs for carbaryl were adopted from the FAO/WHO Codex Alimentarius Commission (Codex) standards by the Pesticide and Agricultural Chemicals Standing Committee. There were no Table 5 MRL Standard entries for carbaryl at the start of the review.

1.3 Residues in cereal grain

Carbaryl is currently approved for uses on both pre- and post-harvest cereal grains. Residue trial data (refer to the previous report) were provided to the review for pre-harvest use only or post-harvest use only.

Residues of carbaryl in stored cereal grain (post-harvest)

Carbaryl products are currently approved for treatment of stored grains and grain storage facilities. The high residue (HR) resulting from the use on bulk grains was previously reported to be 6 mg/kg, with processing factors to wholemeal flour of 0.47 and to wheat bran of 2.4.

Following calculation of the National Estimated Short-Term Intake (NESTI) using the 2009 revised consumption data, the estimate of acute dietary exposure is no longer acceptable (NESTI 140% of ARfD for bran consumption by adults, 100 (101)% for 2–6 years and 100 (104)% for wholemeal flour, 2–6 years).

It is concluded that post-harvest use of carbaryl on stored cereal grain is not longer acceptable and the use should be deleted from labels.

Residues of carbaryl in cereal grain from in-field use (pre-harvest)

Acute exposure calculations based on residue data for preharvest uses of cabaryl as summarised in the previous review report were confirmed as being acceptable (NESTI < 100% of ARfD).

Based on the previously reviewed residues data, the following MRLs are appropriate to support the in-crop uses of carbaryl on cereals with a WHP of 14 days:

Table 1: Recommended Table 1 entries for cereals

GC 0640	Barley	15 mg/kg
GC 0080	Cereal grains [except Barley, Rice and Sorghum]	5 mg/kg
GC 0649	Rice	7 mg/kg
GC 0651	Sorghum	10 mg/kg
CM 0654	Wheat bran, unprocessed	10 mg/kg

Residues in processed grain commodities

In the previous report a Table 4 entry for carbaryl residues in sorghum bran was recommended at 50 mg/kg to account for residues arising from both pre- and post-harvest uses. As the post-harvest use is no longer supported, an MRL for carbaryl in sorghum bran of 20 mg/kg is now recommended.

Likewise, an MRL for carbaryl in wheat bran (unprocessed) is revised from 30 mg/kg recommended previously to 10 mg/kg for inclusion in Table 1 of the MRL Standard. It is appropriate to establish a Table 4

entry for carbaryl of 15 mg/kg for rice hulls based on the outcome of 4.2 (processing factor from rice to rice hulls) × STMR (Supervised Trials Median Residue) of 3.4 mg/kg for rice.

Residues in Cereals, Pulses and Oilseeds stored in carbaryl-treated storage structures

The carbaryl MRLs for cereals proposed above are sufficient to account for residues arising from the approved uses of carbaryl on grain storage structures.

Carbaryl is no longer approved for in-crop use on pulses or oilseeds other than cotton (refer to the preliminary review findings report). However, residues may occur on pulses and oilseeds after storage in structures treated with carbaryl.

National Residue Survey (NRS) monitoring data indicate that when residues occur in oilseeds and pulses they are generally below 0.1 mg/kg (2096 canola samples, 38 with finite residues, 35 with residue ≤ 0.1 mg/kg; pulses 2209 samples, 5 with finite residues, all ≤ 0.1 mg/kg). For canola, three finite residues were observed above 0.1 mg/kg (0.11, 0.18 & 0.42 mg/kg), which were considered to be similar to the residues that may be expected from in-field use of carbaryl.

The following MRLs are recommended to account for residues arising on pulses and oilseeds from the structural uses of carbaryl:

Table 2: Table 1 MRL entries recommended for oilseeds and pulses

VD 0070	Pulses	0.1 mg/kg
SO 0088	Oilseed [except Cotton seed]	0.1 mg//kg

1.4 Residues in fruits and vegetables

Residues trial data were provided for a wide variety of fruit and vegetable crops. The data were presented as full studies, brief trial reports or summary tables of results. Results from all of the trial information provided to the APVMA were used to determine the levels of residues expected to occur in commodities treated according to Australian good agricultural practice (GAP) and, where required, results were scaled down to reflect the maximum approved Australian application rates.

Residues in berry fruit

Grapes

Growcom indicated that the grape industry would like to maintain the use of carbaryl and sought to extend the WHP to cover use when small fruit are on the vines. They suggested several weeks would be manageable by the industry. There were no other submissions regarding grapes.

The argument concerning the extension of the WHP for grapes is not supported by the available data, nor does it satisfy the APVMA from a dietary exposure perspective.

However, the label usage for cutworms, where carbaryl is applied around the base of grapevines, could continue to be supported with appropriate label changes. An MRL of *0.01 mg/kg and a WHP of *Not required when used as directed* would be appropriate for the proposed use.

Raspberries

The use on raspberries involves application of 100 g carbaryl/100 L with a 3-day harvest WHP. The high residue from nine trials under this use was 14.6 mg/kg. Following revision of the consumption data this use is no longer acceptable (NESTI 2–6 years 101% of ARfD).

Data from 15 trials undertaken in the United States of America on raspberries, at dilute spray concentrations of 100–320 g carbaryl, are available where sampling was undertaken 7 or 8 days after application. When corrected for spray concentration, the residues were 1.0, 1.5, 1.6, 1.8, 1.8, 1.8, 2.2, 2.8, 3.0, 3.1, 4.6, 5.0, 6.4, 7.3, 8.4 mg/kg (STMR 2.8 mg/kg). Based on a pre-harvest interval of 7 days the NESTI is acceptable (NESTI 60% and 15% of ARfD for 2–6 years and 2+ years respectively).

The use on raspberries can be supported provided the harvest WHP is increased to 7 days. An MRL of 15 mg/kg for carbaryl in raspberries is appropriate.

Strawberries

A request to consider carbaryl use in commercial strawberry runner production was considered. Carbaryl has limited systemic activity and residues are not expected in strawberry fruit following treatment during runner production. An MRL of 0.01mg/kg for strawberry and a WHP of *Not required when used as directed* would be appropriate for the proposed use.

Blackberries, blueberries and cranberries

Insufficient residues data were available to establish MRLs for blackberries, blueberries and cranberries, and no further residues data have been submitted in response to the preliminary review findings report.

Residues in citrus fruit

After the publication of the preliminary findings in 2004, consultation with the citrus industry and Horticulture Australia Limited (HAL) indicated that the highest rate 0.48 kg ai (active ingredient)/100 L for citrus was not required and could be removed from labels. The next highest rate for application for citrus was 0.1 kg ai/100 L. From samples collected at a 2-day to 90-day pre-harvest interval (PHI), residues in orange and lemon pulp were nil and the residues in peel averaged 0.73 mg/kg (after scaling) and then declined slowly with time. Maximum residues in whole fruit were 2.4 mg/kg, requiring an MRL of 3 mg/kg, lower than

previously recommended (7 mg/kg). NESTI caculations for oranges and lemons are all below < 100%. Therefore the acute dietary exposure to oranges and lemons are acceptable.

Continued use on oranges and lemons is supported with an MRL of 3 mg/kg and WHP of 3 days.

Residues data for tangelos and tangerines were inadequate to assess dietary exposure and no relevant data were available for grapefruit. Uses on citrus other than for oranges and lemons cannot be supported.

Residues in pome fruit

Carbaryl was approved for use on pome fruit as a foliar spray for control of insect pests, and as a foliar spray several months before harvest to aid fruit thinning. As recommended in the previous report, all uses are retained for apples and pears with a WHP of 77 days and an MRL 0.2 mg/kg. Use on loquats only for fruit thinning is supported without a WHP when used as directed, but all other uses have been deleted. The NESTI based on the proposed MRL 0.2 mg/kg is acceptable (77% and 20% of ARfD for 2–6 years and 2+ years respectively).

Residues in stone fruit

In response to the June 2004 draft findings for carbaryl, HAL proposed a WHP of 28–35 days for use of carbaryl in stone fruit, as carbaryl is used primarily during the early fruit development growth stage. The industry was of the opinion that 28–35 days better reflects current GAP. The stone fruit industry suggested that a substantially lower MRL of 0.5 mg/kg be established based on the proposed WHP.

Residues data were available for peaches and plums for periods up to 131 days PHI. There are 13 samples from 24 days onwards. Samples taken later than 24 days PHI did not exceed a carbaryl residue of 0.25 mg/kg. Therefore, it could be possible to set an MRL of 0.5 mg/kg as suggested by the horticulture industry, with a WHP of 35 days. Statistically, the 99th percentile of the residues data set from 24–131 days is a carbaryl residue of 0.212 mg/kg. Therefore there is reasonable confidence that residues will comply with an MRL of 0.5 mg/kg by 28–35 days.

This data also support the uses on apricots and nectarines, as apricots and nectarines tend to reflect the residues profile in peaches and plums. The highest residue value of 0.23 mg/kg could also be used for these fruits when the longer WHP is applied. This results in a maximum NESTI estimation of 92% of the ARfD for stonefruit (excluding cherries).

There are no commercial registrations for carbaryl in cherries apart from home garden use, and there are no relevant data to support this use. Continued approval of the home garden use of carbaryl in cherries cannot be supported, as there are no data available to allow assessmet of dietary exposure or to support MRL establishment.

In conclusion, the continued use of carbaryl in stone fruits except cherries is supported, with an MRL of 0.5 mg/kg and a WHP of 35 days.

Residues in tropical fruit

Public comments

HAL indicated that carbaryl use was primarily during the fruit development stage for tropical fruits and a WHP of 28–42 days was thus proposed. However, no residues data were available for any of the minor tropical fruits to enable MRLs to be determined for the proposed WHP of 28–42 days. Furthermore, the lack of data did not allow the assessment of a suitable WHP for those fruit where carbaryl may be used close to harvest.

The argument concerning use of carbaryl on non-flowering trees is accepted.This use is restricted to trees that are not flowering or not bearing fruit. An MRL of *0.01 mg/kg is recommended to allow more effective control of use.

The argument regarding use of citrus pulp residue data for acute dietary exposure for tropical fruits is not acceptable, due to the different morphology of tropical fruit skins to orange skins.

Further trial data submitted for mango and avocado uses

In 2006 additional residue trials data were submitted for mango and avocado uses. Four trials on mangoes gave maximum residues of 0.26 mg/kg at the WHP of 7 days. The data supported a new MRL of 2 mg/kg for mangoes in conjunction with an extension of the WHP to 7 days. This results in NESTI estimations of 55% and 27% of the ARfD for 2–6 years and 2+ years respectively. A minimum re-treatment period of 14 days is proposed for inclusion on all labels together with a restriction to three applications per crop, in line with the trials.

Two trials on avocadoes were considered in conjunction with the mango trials. Separate analyses found that carbaryl residues were mainly found on the skin. These trials gave maximum residues of 0.55 mg/kg at the WHP of 3 days. The data supported a new MRL of 2 mg/kg for carbaryl in avocados in conjunction with retention of the existing 3-day WHP. The NESTI estimations based on this MRL are 62% and 11% of the ARfD for 2–6 years and 2+ years respectively. A minimum re-treatment period of 14 days is proposed for inclusion on all labels together with a restriction to four applications per crop, in line with the trials.

Residues in cucurbit vegetables

Public comments

The Australian Melon Association stressed that the maintenance of the registration of carbaryl for use in melons is very important to the industry, given the low numbers of chemicals available.

The Association indicated that carbaryl is used on melons in the early stages of the crop cycle, before flowers or fruit are present. Given that the melons then take 5–10 weeks to develop before harvest, they could accommodate a longer WHP, such as 2 weeks.

They further contended that, because the melons have an inedible skin, taking this into account could satisfy the acute dietary exposure excesses. No data were supplied.

The acute dietary intake calculation indicated that, for watermelons, the exposure was equivalent to 1819% of the ARfD. There are no relevant data available to allow determination of a longer WHP to reduce the dietary exposure, to allow use during the flowering and fruiting period.

However, as carbaryl is non-systemic, and if use on melons is restricted to pre-flowering, the use of carbaryl on melons is acceptable up to first flowers appearing, with label variations and Table 1 changes to include an MRL of *0.01 mg/kg for fruiting vegetables, cucurbits along with a WHP of *Not required when used as directed*.

Residues in root and tuber vegetables

Residues data allowed for establishment of MRLs of 0.1 mg/kg for potatoes, 2 mg/kg for turnips (swede) and 0.5 mg/kg for beetroot, as recommended in the previous review report. Based on the residue data for potatoes, it is appropriate to allow continued use on sweet potatos. An MRL of 0.1 mg/kg with a WHP of 3 days is recommended.

There were no suitable residues data available for carrots and parsnips to allow the establishment of a suitable MRL for these commodities. These uses have been deleted from the label.

Residues in leafy vegetables, fruiting vegetables other than cucurbits, legume vegetables, stalk and stem vegetables, bulb vegetables and brassica vegetables

As recommended in the previous report, uses on these commodities can no longer be supported owing to acute dietary exposure concerns.

1.5 Residues in tree nuts

Uses of carbaryl on macadamia nuts and pecan nuts were supported in the previous report with an MRL of 2 mg/kg and a WHP of *Not required when used as directed*.

Use of carbaryl on coconuts to control palm leaf beetle was previously authorised by a Queensland Board Approval and has since been incorporated onto product labels. This use is restricted to trees that are not flowering or not bearing fruit. An MRL entry in Table 1 of the MRL Standard of *0.01 mg/kg is recommended for this use.

1.6 Residues in animal feeds

Recommendations for animial feed community MRLs remain as previously proposed, except for the variation to the sorghum bran MRL of 20 mg/kg (previously recommended at 50 mg/kg based on residues arising from pre- and post-harvest use) and the addition of a rice hulls MRL of 15 mg/kg.

1.7 Non-food and pre-fruiting uses

Registered carbaryl products may be used in a variety of non-food (human or livestock) situations: as an insecticide in commercial, industrial and domestic areas, tobacco storage sheds and rights of way, in non-crop areas in general, ornamentals, lawns, elm trees (in non-crop areas), kenaf, Duboisia and rosella, and for disinfestation of grain storage buildings.

Carbaryl products are also used on food crops where residues are not expected (such as uses before flowering). Table 5 entries of the MRL Standard were recommended in the previous review report for uses in various food crops where residues were not expected to occur in the harvested product. Following further consideration it is recommended that these are replaced with the following Table 1 entries:

Table 3: Recommended additions to Table 1 of the MRL Standard

TN 0665	Coconut	*0.01
VC 0045	Fruiting vegetables, Cucurbits	*0.01
FI 0335	Feijoa	*0.01
FB 0269	Grapes	*0.01
FT 0336	Guava	*0.01
FT 0300	Jaboticaba	*0.01
FI 0338	Jackfruit	*0.01
FI 0342	Longan	*0.01
FI 0343	Litchi	*0.01
FI 0358	Rambutan	*0.01
FB 0275	Strawberry	*0.01

* Denotes that the MRL has been set ‘at or about’ the limit of analytical detection.

The following restraint is recommended to be added to product labels: ‘DO NOT use on rosella or kenaf crops that will be used for human consumption’.

1.8 Animal commodity maximum residue limits

Since the APVMA review began, new methodology for the determination of carbaryl residues in animal tissues has been considered by the JMPR. The new method includes an acid hydrolysis step (30-minute reflux in conc. HCl) which liberates conjugated parent. Method comparisons confirm that the major proportion of parent is present in tissues in conjugated form.

Plant metabolism studies reviewed by the JMPR (radish, leaf lettuce, soya bean, and apple) indicate that conjugated carbaryl is not a major component of the total residue in plants. Analytical methods for determination of carbaryl in plant commodities do not include an acid hydrolysis step. The residue of concern for plant commodities remains free carbaryl.

It is appropriate to revise Australian animal commodity MRLs recommended in the previous review report to account for the method used in establishing the Codex MRLs. Although most national MRLs for animal commodities are currently based on free carbaryl, the new methodology may be used in residue monitoring of imports, especially by countries that reference Codex MRLs. For transparency it is also appropriate 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*.

The livestock dietary burden for cattle was previously estimated to be 341 ppm, resulting from grazing/feeding of grass pastures. The feeding study included a feeding level of 347 ppm, approximating the estimated burden of 341 ppm. Observed residues at the 347 ppm feeding level and recommended MRLs are given in the table below. Based on available information, 'muscle' in the study is trimmed meat rather than fat-free muscle.

Table 4: Observed residues and recommended MRLs for mammalian products

	RESIDUES (mg/kg)	CURRENT MRL (mg/kg)	MRL RECOMMENDATION (mg/kg)
Muscle (composite thigh & loin)	0.03, 0.03, 0.05	T0.2	0.07 (meat)
Liver	0.74, 1.0, 1.0	T0.2	3
Kidney	1.9, 2.1, 2.3	T0.2	3
Fat (composite perirenal & omental)	0.02, 0.03, 0.12[a]		
Milk	Max 0.07		0.1

a Carbaryl has a log Kow of 1.85 so is not likely to be fat soluble or bioaccumulate. In a laying hen metabolism study reviewed by the JMPR, residues of carbaryl in abdominal fat were 0.004 mg/kg and not quantifiable in thigh muscle. The 2002 JMPR reported that little reliable metabolism data for mammalian farm animals are available. The residue of 0.12 mg/kg in fat at a feeding level of 347 ppm was higher than the highest residue (0.07 mg/kg) observed in fat at a feeding level of 1437 ppm where residues in muscle were also observed to approximate those in fat. The study authors disregarded the result of 0.12 mg/kg, as did the JMPR. The residue of 0.12 mg/kg in fat has also been disregarded in recommending MRLs in Australia.

The MRLs recommended have increased from 0.02 mg/kg to 0.07 for meat, 0.02 mg/kg to 0.1 mg/kg for milk, and 0.2 mg/kg to 3 mg/kg for edible offal, compared with MRLs recommended in the previous review report.

Poultry MRLs in the previous report were established based on dietary exposure to feeds only, and not to account for direct treatment. The previous recommendations remain appropriate. (In relation to the use of registered carbaryl products as direct treatments to poultry, the APVMA was not satisfied that the use of the products would not result in residues in poultry commodities exceeding the MRLs established and these products were cancelled in January 2007 as an outcome of Part 1 of the carbaryl review.)

A registered carbaryl product was used as a direct (external) treatment to pigs. The direct treatment use pattern involved application to wetness using a 0.5% solution (50 g ai/10 L). A slaughter period of 7 days applied to this use. Residues in pigs one day after spraying with 1% carbaryl solution were below the Level of Detection[1]. Direct treatment at the label rate (0.5% solution) with a 7-day WHP is thus expected to have no contribution to the residues of the pig commodites and residues will comply with mammalian MRLs.

These changes in mammalian MRLs and residue 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.

1.9 Dietary exposure

In December 2002, the Acceptable Daily Intake (ADI) for carbaryl was increased from 0.004 to 0.008 mg/kg bw/day and the ARfD was set at 0.01 mg/kg bw[2].

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 derived from the 1995 National Nutrition Survey of Australia asd associated surveys. NESTI calculations are conservative estimates of acute exposure (24-hour period) to chemical residues in food.

The calculations presented in the previous report were revised in line with the 2009 FSANZ revision of consumption figures (see Appendix). 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.

Long-term dietary exposure

The chronic dietary exposure to carbaryl was estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with World Health Organization Guidelines and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for carbaryl is < 20% of the ADI.

1 Claborn HV, Roberts RH, Mann HD, Bowman HC, Ivey MC, Weidenbach CP & Radeleff RD (1963). Residues in body tissues of livestock sprayed with Sevin or Sevin in the diet. Journal of Agricultural and Food Chemistry 11:74–76: JMPR 1966.

2 The OCSEH recommended a new ARfD and revised the ADI for carbaryl in its report dated December 2002.

DIAMOND modelling of chronic dietary exposure 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[3] 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.

1.10 Trade

As an outcome of these decisions it is not likely that residues observed in traded produce will be higher than those observed under the currently approved use patterns.

1.11 Recommendations

Recommendations for variation to MRLs have been made throughout the review. Some of those recommendations were implemented before the review was finalised.

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

Table 5: Changes to Table 1 of the MRL Standard

		MRL (mg/kg)	
COMPOUND	FOOD	AT START OF REVIEW	ON FINALISATION
Carbaryl			
Variations to Table 1 entries			
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[a]
FS 0013	Cherries	5	DELETE

3 Available from the FSANZ website at: www.foodstandards.gov.au/scienceandeducation/publications/20thaustraliantotaldietsurveyjanuary2003/

		MRL (mg/kg)	
COMPOUND	FOOD	AT START OF REVIEW	ON FINALISATION
FC 0001	Citrus fruits	7	DELETE
SO 0691	Cotton seed	1	3
FI 0332	Custard apple	5	DELETE[a]
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
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

COMPOUND	FOOD	MRL (mg/kg)	
		AT START OF REVIEW	ON FINALISATION
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
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[a]
VR 0574	Beetroot	ADD	0.5
GC 0080	Cereal grains [except Barley, Rice and Sorghum]	ADD	5[ab]
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[a]
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.

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

b Exception for rice to be added on review finalisation

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

Table 6: Recommended changes to Table 3 of the MRL Standard

COMPOUND	RESIDUE
DELETE	
Carbaryl	Carbaryl
ADD	
Carbaryl	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 7: Changes to Table 4 of the MRL Standard

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

a 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 8: Recommended changes to Table 5 of the MRL Standard

SUBSTANCE	USE
ADD	
Carbaryl	As an insecticide in non-crop areas including commercial, industrial and domestic areas, tobacco storage sheds and rights of way
	As an insecticide on ornamentals and other non-food or animal feed crops and trees

References

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APPENDIX: NESTI CALCULATIONS FOR USES SUPPORTED BY THE REVIEW

			NESTI (% ARfD)	
COMPOUND	FOOD	MRL (mg/kg)	2-6 YEAR OLD	2+ YEAR OLD
Carbaryl				
FI 0326	Avocado	2	62	11
GC 0640	Barley	15	2	9
VR 0574	Beetroot	0.5	69	11
GC 0080	Cereal grains [except Barley and Sorghum]	5	15	9
TN 0665	Coconut	*0.01	< 1	< 1
SO 0691	Cotton seed	3	31	12
VC 0045	Fruiting vegetables, Cucurbits	*0.01	6	6
MO 0105	Edible offal (Mammalian)	3	8	31
PE 0112	Eggs	*0.02	1	< 1
FI 0335	Feijoa	*0.01	4	1
FB 0269	Grapes	*0.01	5	2
FT 0336	Guava	*0.01	3	1
FT 0300	Jaboticaba	*0.01	2	< 1
FI 0338	Jackfruit	*0.01	9	1
FC 0204	Lemon	3	41	7
FI 0342	Longan	*0.01	3	1
FI 0343	Litchi	*0.01	3	1
TN 0669	Macadamia nut	2	14	20
FI 0345	Mango	2	55	27
MM 0095	Meat [mammalian]	0.07	7	4
ML 0106	Milks	0.1	55	21
SO 0088	Oilseed [except cotton seed]	0.1	1	1
FC 0004	Oranges, Sweet, Sour	3	64	24
TN 0672	Pecan	2	10	20
FP 0009	Pome fruits	0.2	77	20
VR 0589	Potato	0.1	18	7
PO 0111	Poultry, Edible offal of	0.2	2	6
PM 0110	Poultry meat	*0.02	2	1
VD 0070	Pulses	0.1	3	1
FI 0358	Rambutan	*0.01	3	1
FB 0272	Raspberries, Red, Black	15	58	14
GC 0651	Sorghum	10	28 (NC)	48 (NC)

			NESTI (% ARfD)	
COMPOUND	FOOD	MRL (mg/kg)	2-6 YEAR OLD	2+ YEAR OLD
FS 0012	Stone fruits [except cherry]	0.5	92	29
FB 0275	Strawberry	*0.01	1	< 1
VR 0497	Swede	2	32	52
VR 0508	Sweet potato	0.1	18	6
VR 0506	Turnip, Garden	2	32	18
CM 0654	Wheat bran, unprocessed	10	3	4

NC is 'not consumed'

* the MRL has been set 'at or about' the limit of analytical detection.