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The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

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PROPOSED REGULATORY DECISION TO CANCEL REGISTRATIONS OF CHLORPYRIFOS HOME GARDEN AND DOMESTIC PEST CONTROL PRODUCTS

1. The APVMA propose to cancel the registrations of the 27 chemical products (**products**) listed in the table in **Annexure A** under section 34AA of the Agricultural and Veterinary Chemicals Code in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (**Code**) (**the proposed decision**).

2. This document sets out the APVMA's reasons for the proposed decision, as required by paragraph 34AB(2)(c) of the Code.

Legal Framework

3. Unless otherwise indicated, references to sections are references to the Code.

RECONSIDERATION OF REGISTRATION

4. Section 31 of the Code provides that the APVMA may reconsider, relevantly, the registration of a chemical product. Reconsideration process is to be undertaken in accordance with the provisions of Division 4 of Part 2 of the Code.

Notification and provision of information

5. Subsection 32(1) of the Code provides that the APVMA must notify the holder of the registration of the matters it proposes to deal with in the reconsideration and its reasons for so proposing, and invite the holder to make a written submission on the reconsideration. The holder will also be required by the notice to give to the APVMA information relevant to the reconsideration that is either required by the notice, or that the holder is aware of.

6. Subsection 32(2) of the Code also provides for the APVMA to, if it considers it desirable to do so, inform any persons, in any manner that it thinks appropriate, that the APVMA proposes to reconsider, or is reconsidering, the registration. Subsection 32(2A) sets out the requirements of such a notice.

7. Under section 33 of the Code, the APVMA may also require, by written notice, the holder to conduct trials or experiments, or provide information or samples, for the purposes of the reconsideration.

Affirmation

8. Subsection 34(1) of the Code relevantly provides that the APVMA must affirm the registration of a chemical product if, and only if, it is satisfied that the product:

8.1 meets the safety criteria, the trade criteria and the efficacy criteria;[1] and

8.2 complies with any requirement prescribed by the regulations.[2]

9. Paragraph 34(3)(a) sets out the following matters that must be considered by the APVMA for the purposes of subsection 34(1):

(i) any information given, or submissions made, to the APVMA in response to a notice given under subsection 32(1); and

(ii) any submissions made to the APVMA in response to an invitation under paragraph 32(2A)(b) or 34AB(2)(f); and

(iii) any information given by the holder in response to an invitation given by the APVMA (whether or not under this Code) in relation to the constituent, product or label; and

(iv) any information, report, results or sample given to the APVMA in response to a notice given under section 33; and

(v) any information given to the APVMA as required by section 161 in relation to the constituent, product or label; and

[1] Code, paragraph 34(1)(b).
[2] Code, paragraph 34(1)(d).

(vi) any other information that it considers necessary to enable it to make a decision on the reconsideration.

10. Paragraph 34(3)(b) provides that the APVMA must not take into account any submission, information, report, results or sample that is not covered by paragraph 34(3)(a).

11. If the APVMA is not satisfied as mentioned in subsection 34(1), but it is satisfied that the relevant particulars or conditions of registration of the product can be varied in such a way as to allow the registration to be affirmed (ie if the relevant particulars or conditions of registration can be varied so as to allow APVMA to be satisfied of the relevant matters in subsection 34(1)), then the APVMA must vary the relevant particulars or conditions accordingly.[3] It must then affirm the registration.[4]

Suspension or cancellation

12. If the APVMA does not affirm the registration, subsection 34AA(1) of the Code requires the APVMA to suspend or cancel the registration. In particular, if variation(s) to the relevant particulars and/or conditions of registration cannot remedy whatever issue or issues is or are preventing the APVMA from being satisfied as mentioned in subsection 34(1), the registration must be suspended or cancelled.

NOTICE REQUIREMENTS

13. Relevantly, if the APVMA proposes to vary the relevant particulars or conditions, or suspend or cancel a registration, section 34AB of the Code requires notice of that proposed decision to be given to the holder and to other persons informed of the reconsideration as mentioned in subsection 32(2). Such notice must comply with the requirements contained in subsection 34AB(2). These include a requirement that the notice include a draft statement of reasons for the proposed course of action,[5] and that the notice '*invite written submissions from the holder or other persons within 3 months*'.[6]

[3] Code, paragraph 34A(1).
[4] Code, subsection 34(1).
[5] Code, paragraph 34AB(2)(c).
[6] Code, paragraph 34AB(2)(f).

Material on which the APVMA findings are based

14. In making this proposed decision the APVMA has had regard to:

14.1 advice from the Chemical Review section of the APVMA as to the relevant particulars of the products, specifically the APVMA product registration number, the distinguishing name of the chemical product, registration holder and label approval number as provided in the table containing list of products under **Annexure A**

14.2 advice from the Principal Toxicologist of the APVMA as to the appropriate means by which to determine the acceptable daily intake and acute reference dose for chlorpyrifos set out in the report entitled *Reconsideration of chlorpyrifos—Toxicology update, June 2019*;

14.3 advice from the Principal Toxicologist based on data generated by the Health Assessment Team of the APVMA regarding the levels of exposure to chlorpyrifos which may reasonably be anticipated to result from the use of the products in a residential and public setting by persons other than professionals, set out in a report entitled *Reconsideration of chlorpyrifos—Residential exposure and public space use exposure assessment and risk characterisation update, June 2019*;

14.4 advice commissioned by the APVMA's Scientific Assessment and Chemical Review team regarding the risk of harm to animals associated with home garden and urban use of the products, set out in a report entitled *Reconsideration of chlorpyrifos—Supplementary environment assessment report Part —Home garden, domestic and certain non-agricultural uses, June 2019*;

14.5 relevant provisions of the Code;

14.6 APVMA's policy on Worker health and safety risk assessments;[7]

14.7 information given in response to 78 notices given under subsection 32(1);

14.8 submissions made to the APVMA in response to an invitation under paragraph 32(2A)(b); and

14.9 information given to the APVMA in response to two notices given under section 33.

15. In the APVMA's view, consideration of the Reconsideration of chlorpyrifos–Toxicology update (2019), the Reconsideration of chlorpyrifos—Residential exposure and public space use exposure assessment and risk characterisation update (Exposure assessment and risk characterisation report, 2019), the Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) and the APVMA's policy on Worker health and safety risk assessments is necessary to enable me to make a decision on the reconsideration.[8] The APVMA is not aware of any other information that falls within paragraph 34(3)(a) of the Code that requires consideration.

[7] APVMA, *Worker Health and Safety Risk Assessments undertaken by the APVMA,* 12 June 2018 available at apvma.gov.au/node/31421.
[8] Code, paragraph 34(3)(a)(vi).

Material findings of fact

16. Based on the advice the APVMA has had regard to, the APVMA propose making the following findings of fact which are material to the proposed decision:

16.1 chlorpyrifos is hazardous to mammals (including human beings)—that is, it has the *potential* to cause harm;

16.2 the types of adverse effects from exposure to chlorpyrifos are dependent on the level of exposure, with more severe adverse effects occurring as the level of exposure increases;

16.3 exposure to chlorpyrifos at levels that result in detectable inhibition of blood cholinesterases is a serious neurodevelopmental and neuro-behavioural developmental health hazard for humans;

16.4 the acceptable daily intake (**ADI**) for chlorpyrifos is 0.001 mg/kg bw/day (1 µ/kg bw/day);

16.5 the acute reference dose for chlorpyrifos is 0.03 mg/kg bw;

16.6 chlorpyrifos exposure reasonably expected in connection with non-professional residential use of the products will likely exceed the acute reference dose;

16.7 post-application re-entry intervals and personal protective equipment (apart from gloves) do not represent realistic risk mitigation strategies for non-professional users in a residential setting;

16.8 the use of the products in a residential setting is likely to have an effect that is harmful to human beings;

16.9 the use of the products by non-professionals in a residential setting poses an undue hazard to the safety of people exposed to said products during their handling;

16.10 the chronic avian dietary no observed effect concentration for chlorpyrifos is 25 mg/kg;

16.11 the acute avian oral lethal dose (LD_{50}) is 28.9 mg/kg bw;

16.12 the use of the products in a residential setting, including application to turf at rates that exceed 850 g ac/ha poses an unacceptable risk to birds;

16.13 granular chlorpyrifos products used in a residential setting are prone to being applied at application rates in excess of 850g ac/ha; and

16.14 the use of granular chlorpyrifos products in a residential setting is likely to have an unintended effect that is harmful to animals.

REASONS

Issue 1—do the products meet the safety criteria, the trade criteria and the efficacy criteria? [paragraph 34(1)(b)]

SAFETY CRITERIA

17. The products listed in **Annexure A** are chemical products within the definition of section 3 of the Code. The safety criteria are set out in subsection 5A(1) of the Code, which is in the following terms:

(1) An active constituent or chemical product meets the safety criteria if use of the constituent or product, in accordance with any instructions approved, or to be approved, by the APVMA for the constituent or product or contained in an established standard:

(a) is not, or 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

(b) is not, or would not be, likely to have an effect that is harmful to human beings; and

(c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

18. Subsection 5A(3) sets out considerations that the APVMA must, and may, have regard to for the purposes of being satisfied as to whether a chemical product meets the safety criteria; namely:

a) [the APVMA] must have regard to the following:

(i) the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;

(ii) the relevant poison classification of the product under the law in force in this jurisdiction;

(iii) how the product is formulated;

(iv) the composition and form of the constituents of the product;

(v) any conditions to which its registration is, or would be, subject;

(vi) any relevant particulars that are, or would be, entered in the Register for the product;

(via) whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);

(vii) any matters prescribed by the regulations; and

b) [the APVMA] may have regard to one or more of the following:

(i) the acceptable daily intake of each constituent contained in the product;

(ii) any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under subsection 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under subsection 82(4) of that Act;

(iii) whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves;

(iv) the stability of the product;

(v) the specifications for containers for the product;

(vi) such other matters as it thinks relevant.

19. Regulation 8AB of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Cth) (**the Agvet Code Regulations**) prescribes the following matters for chemical products, pursuant to subparagraph 5A(3)(a)(vii):

(1) For subparagraph 5A(3)(a)(vii) of the Code, the following are prescribed matters for a chemical product:

a) for all chemical products—the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product;

b) for a product manufactured in Australia—whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code;

c) for a product manufactured outside Australia—whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code;

d) for a molluscicide in the form of a bait and of which the active constituent is metaldehyde:

(i) whether the product contains sufficient green pigment or dye to colour the bait a distinctive green colour; and

(ii) whether the product contains, in the bait, any bone meal or other product of animal origin;

e) for a molluscicide in the form of a bait and of which the active constituent is methiocarb:

(i) whether the product contains sufficient blue pigment or dye to colour the bait a distinctive blue colour; and

(ii) whether the product contains, in the bait, any bone meal or other product of animal origin;

f) for an agricultural chemical product to be applied to seeds to be stored before planting or sowing—whether the product contains sufficient pigment or dye to colour the seed to enable the seed to be readily distinguished from seed to which the product has not been applied.

(2) However, paragraphs (1)(b) and (c) do not apply if the product is prescribed under subregulation 59(1) for the purposes of section 120A of the Code.

Paragraphs 5A(1)(c)

20. Paragraphs 5A(1)(a) and (b) provide that a product will only satisfy the safety criteria if it is not, or would not be:

20.1 an undue hazard to the safety of people exposed to it during its handling or using anything containing its residues; and

20.2 likely to have an effect that is harmful to human beings.

21. In relation to determining whether the products satisfy these requirements, the APVMA has had regard to relevant advice from the Principal Toxicologist. That advice is set out in the Reconsideration of chlorpyrifos—Toxicology update (2019). The Reconsideration of chlorpyrifos—Toxicology update (2019) confirms that exposure to chlorpyrifos at levels higher than those that inhibit blood cholinesterases (ie 'high dose chlorpyrifos exposure') results in adverse effects, particularly adverse effects on neurodevelopment and neurobehavioural developmental.[9]

a) Acceptable daily intake

(i) Identifying an appropriate point of departure

22. I note that the ADI for the constituents in a chemical product is a matter to which the APVMA may have regard in determining whether the products meet the safety criteria.[10] The Reconsideration of chlorpyrifos—Toxicology update (2019) evaluated the study that presently forms the basis for the APVMA ADI for chlorpyrifos (0.003 mg/kg bw/day). That study is entitled *Safety evaluation of DOWCO*

[9] Reconsideration of chlorpyrifos—Toxicology update, 2019, pages 9–10.
[10] Code, s 5A(3)(b)(i).

179 in human volunteers (**Coulston and Golberg,** 1972).[11] The purpose of that evaluation was to provide advice as to whether Coulston and Golberg continues to represent an appropriate departure point for the establishment of the ADI.

23. In the Reconsideration of chlorpyrifos—Toxicology update (2019), the Principal Toxicologist found that there were certain shortcomings in the quality of the Coulston and Golberg study. These are addressed in detail at pages 14–16 of Reconsideration of chlorpyrifos—Toxicology update (2019). The APVMA accepts the Principal Toxicologist's analysis of the Coulston and Golberg study set out in the Reconsideration of chlorpyrifos—Toxicology update (2019), and the APVMA adopts the Principal Toxicologist's conclusion that it no longer represents a reliable point of departure for the calculation of the ADI for chlorpyrifos for humans.[12] As discussed in the following paragraphs, the APVMA also adopts the Principal Toxicologist's conclusion that the current ADI for chlorpyrifos (0.003 mg/kg bw/day) is no longer reliable for regulatory purposes.[13]

24. In the Reconsideration of chlorpyrifos—Toxicology update (2019), the Principal Toxicologist recommended that the APVMA establish a new ADI for chlorpyrifos based on the recent series of studies in young and adult rat populations performed by DOW in 2010[14] and Marty et al in 2012.[15] In these studies, the No Observable Effect Level (**NOEL**) for inhibition of blood cholinesterases for rats from post-natal day 11 of age to adulthood was 0.1 mg/kg bw/day (consistently five-fold lower than the threshold for inhibition of brain cholinesterases in this species).[16] The Reconsideration of chlorpyrifos—Toxicology update (2019) notes that this point of departure is also supported by toxicological thresholds in other studies that have been evaluated by the APVMA.[17] The APVMA therefore accepts that the NOEL of 0.1 mg/kg bw/day is the appropriate point of departure for the establishment of a new ADI.

(ii) Uncertainty factors

25. In the Reconsideration of chlorpyrifos—Toxicology update (2019), the Principal Toxicologist recommended that an uncertainty factor of 10 should be applied to account for intra-species variations.[18] The Principal Toxicologist further recommended that an uncertainty factor of 10 be applied to account for inter-species variations.[19] Thus the total recommended uncertainty factor to be applied is 100.[20] The APVMA is advised, and the APVMA accepts, that the application of such uncertainty factors is consistent with established approaches to regulatory toxicology.

(iii) New acceptable daily intake

26. In the Reconsideration of chlorpyrifos—Toxicology update (2019), the Principal Toxicologist advised that the ADI is calculated by dividing the NOEL by the uncertainty factor (in this case, 100) and proposed that the new ADI 0.001 mg/kg bw/day (1 µ/kg bw/day).[21]

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[11] Coulston F, Goldberg L, Griffin T,*Safety evaluation of DOWCO 179 in human volunteers* (1972) Institute of Experimental Pathology and Toxicology, Albany Medical College, Albany, New York, USA. Dow AgroSciences.

[12] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 16.

[13] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 20.

[14] Dow, *Comparison of cholinesterase (che) inhibition in young adult and preweanling CD rats after acute and repeated chlorpyrifos or chlorpyrifos-oxon exposures*, 2010. The Dow Chemical Company Study ID 091107, pp 1–1062. 2010.

[15] Marty MS, Andrus AK, Bell MP, Passage JK, Perala AW, Brzak KA, Bartels MJ, Beck MJ, Juberg DR. *Cholinesterase inhibition and toxicokinetics in immature and adult rats after acute or repeated exposures to chlorpyrifos or chlorpyrifos-oxon*. Regul Toxicol Pharmacol. 2012 Jul; 63(2):209-24. doi: 10.1016/j.yrtph.2012.03.015. Epub 2012 Apr 7. PubMed PMID: 22504667.

[16] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 20.

[17] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 20.

[18] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 20.

[19] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 20.

[20] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 20.

[21] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 20.

27. On the basis of this advice, the APVMA propose finding that 0.001 mg/kg bw/day (1 µ/kg bw/day) is the new ADI for chlorpyrifos.

b) Acute reference dose

(iv) Identifying an appropriate point of departure

28. In the Reconsideration of chlorpyrifos—Toxicology update 2019, the Principal Toxicologist also evaluated the regulatory study that forms the basis for the APVMA's current human acute reference dose for chlorpyrifos (0.1 mg/kg bw/day).[22] This study is entitled *a rising dose toxicology study to determine the no-observable-effect-levels (NOEL) for erythrocyte acetylcholinesterase (AChE) inhibition and cholinergic signs and symptoms of chlorpyrifos at three dose levels* (**Kisicki** et al, 1999).[23]

29. In the Reconsideration of chlorpyrifos—Toxicology update (2019), the Principal Toxicologist advised that the study remains the best available acute exposure data in humans that is currently available to the APVMA, but noted that there were statistical power limitations (small *n* compared with modern human clinical trial standards).[24] The APVMA accepts the Principal Toxicologist's conclusions in respect of the quality and reliability of Kisicki (1999), as set out in the Reconsideration of chlorpyrifos—Toxicology update (2019).

30. On this basis, the APVMA accepts the Principal Toxicologist's recommendation that the current human acute, single dose NOEL for inhibition of plasma cholinersterase of 0.1 mg/kg bw derived from Kisicki (999) be retained. This forms the point of departure for the calculation of the acute reference dose.

(v) Uncertainty factors

31. In the Reconsideration of chlorpyrifos—Toxicology update (2019), the Principal Toxicologist recommended an uncertainty factor of 10 should be applied for intra-species variations in calculating the acute reference dose and advised that no inter-species uncertainty factor is necessary.[25] Because of the statistical power limitations and other issues identified with Kisicki (1999), The Principal Toxicologist also recommended an additional uncertainty factor of $10^{0.5}$-fold should be applied to account for any remaining uncertainties.[26] The APVMA accepts these recommendations, and therefore propose finding that the total uncertainty factor to be applied is $10 \times 10^{0.5}$.

(vi) New acute reference dose

32. In the Reconsideration of chlorpyrifos—Toxicology update (2019), the Principal Toxicologist proposed that the new acute reference dose is $1/(10 \times 10^{0.5}) \approx 0.03$ mg/kg bw (30 µg/kg bw). On the basis of this advice, the APVMA propose finding that 0.03 mg/kg bw (30 µg/kg bw) is the new acute reference dose.

c) Exposure assessments

33. Having established the ADI and acute reference dose for chlorpyrifos, advice was sought from the Principal Toxicologist to assess the anticipated exposure to chlorpyrifos associated with the registered uses of the products. The aim of the exposure assessments was to establish whether reasonably

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[22] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 7.

[23] Kisicki JC, Seip CW, Combs ML, *A rising dose toxicology study to determine the no-observable-effect-levels (NOEL) for erythrocyte acetylcholinesterase (AChE) inhibition and cholinergic signs and symptoms of chlorpyrifos at three dose levels* (1999) Dow Agrosciences. Report No. DR#K-044793-294.

[24] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 19.

[25] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 22.

[26] Reconsideration of chlorpyrifos—Toxicology update, 2019, page 22.

anticipated exposures to relevant organisms (including human beings) would exceed whichever of the two health guidance values represented the most appropriate point of departure in any given case.

34. Exposure assessments and risk characterisations were conducted in respect of three relevant scenarios:

34.1 professional applicators who mix, load and apply chlorpyrifos for use in child-accessible public spaces and domestic/residential areas;

34.2 professional applicators who re-enter chlorpyrifos-treated, child-accessible public spaces and domestic/residential areas; and

34.3 non-professional uses of chlorpyrifos in child-accessible residential settings.

35. The results of the exposure assessments and risk characterisations, and the assumptions upon which the exposure assessments and risk characterisations proceeded, are stated in the Exposure assessment and risk characterisation report (2019). The APVMA has reviewed those assumptions (set out below) and the APVMA considers them to be reasonable.

36. The APVMA has also had regard to the particular models used in the risk assessments. The APVMA accepts these as being the most relevant and robust models available for this purpose.

(vii) Scenario 1: Professional applicators who mix, load and apply chlorpyrifos for use in child-accessible public spaces and domestic/residential areas

37. The assumptions upon which the exposure assessments and risk characterisations conducted in respect of this scenario, stated in the Exposure assessment and risk characterisation report (2019), were as follows:[27]

- professional trained applicators mixed, loaded and applied chlorpyrifos
- professional use in child-accessible public spaces involves regular and repeated occupational exposure to chlorpyrifos over a long period of time. Accordingly the ADI was regarded as the most appropriate human health based guidance value for such uses. The relevant POD was 0.1 mg/kg bw/day which is the no observed adverse effect level (NOAEL) for inhibition of blood cholinesterases in rats following repeated chlorpyrifos exposure (APVMA 2019). A margin of exposure (MOE) of 100 was applied to account for inter and intra-species uncertainties
- professional applicators were assumed to be trained, competent, experienced and compliant users of personal protective equipment
- professional operators were assumed to be trained in, and were competent, experienced and compliant users of relevant application techniques and equipment
- professional applicators were assumed to have a high degree of competence regarding the interpretation of label requirements
- professional operators were assumed to be capable of accurately measuring work rates. A high level of compliance with label-specified mandatory maximum work rates was assumed
- the assessments assumed that amongst professional applicators there would be a high level of compliance with label directed mandatory minimum re-entry intervals
- the exposure and risk characterisation assessments assumed, as a worst case, that a single operator would perform all steps in the use of chlorpyrifos products ie a single operator mixes, loads and applies the pesticide during product use
- the minimum, base-level personal protective equipment was assumed to consist of a long sleeved shirt, long pants, boots and socks or equivalent single layer of clothing (eg coveralls fastened at the neck and wrist). This was assumed to be always used when mixing, loading and applying chlorpyrifos. Personal protective equipment, if required for risk management, was applied in addition to this minimum base level of equipment
- consistent with APVMA's current data on chlorpyrifos use in Australia, the evaluations assumed that 100 per cent closed systems would not be used during mixing, loading and application

[27] Exposure assessment and risk characterisation report, 2019, pages 8–9.

- the assessments assumed that concurrent co-exposures to other anticholinesterase products (the effects of which are likely to be at least additive to those of chlorpyrifos due to their common mode of action) did not occur
- the assessments assumed that there was only one single type of use and/or activity per operator per day; for example the same operator would not undertake chlorpyrifos hand wand treatment of a hedge plus performing chlorpyrifos application to lawns using a mechanical spreader on the same work day
- Work rates are based on label information and information contained in NOHSC 2001, Compendium of Farming Practices, National Occupational Health & Safety Commission, Canberra.

38. As stated above, the APVMA considers these assumptions to be reasonable.

39. The results of the exposure assessments and risk characterisations conducted in respect of this scenario are set out in Appendix 1 of the Exposure assessment and risk characterisation report (2019).

40. On the basis of those results, the Principal Toxicologist recommended that all uses of chlorpyrifos by professional applicators who mix, load and apply chlorpyrifos for use in child-accessible public spaces and domestic/residential areas, other than those appearing in Table 2 of the Exposure assessment and risk characterisation report (2019), be found to give an unacceptable margin of exposure. Table 2 is set out an **Annexure B** to this statement of reasons.

41. The APVMA accepts as correct the analysis and conclusion of the Principal Toxicologist in relation to this scenario as set out in the Exposure assessment and risk characterisation report (2019).

42. The APVMA therefore propose finding that the use of chlorpyrifos by professional applicators who mix, load and apply chlorpyrifos for use in child-accessible public spaces and domestic/residential areas is likely to be harmful to human beings, except insofar as the products are used by professional applicators in the circumstances appearing in Table 2 of the Exposure assessment and risk characterisation report (2019) (see **Annexure B**). The APVMA propose finding that the use of the product by professional applicators in the circumstances appearing in Table 2 of the Exposure assessment and risk characterisation report (2019) are not likely to be harmful to human beings.

(viii) Scenario 2: Professional applicators who re-enter into chlorpyrifos-treated, child-accessible public spaces and domestic/residential areas

43. The assumptions upon which the re-entry exposure assessments and risk characterisations conducted in respect of this scenario, stated in the Exposure assessment and risk characterisation report (2019), were as follows:[28]

- a maximum acceptable re-entry interval of one day was applied to ensure drying of the applied material
- people do not swim in water bodies that have been treated with chlorpyrifos for mosquito control. For this reason re-entry intervals for chlorpyrifos treated water and surface waters were not calculated
- re-entry exposure was assumed to be via dermal exposure. Inhalation exposures under these circumstances were regarded as toxicologically negligible
- only the most exposure-intensive activities for each situation were evaluated (worst case scenario)
- mandatory minimum re-entry intervals for child-accessible public spaces were not regarded as a reliable risk management approach
- multiple re-entries into chlorpyrifos treated, child-accessible public spaces were assumed to occur. Accordingly the most appropriate human health based guidance value for these circumstances was the ADI. This approach is supported by the variable, and potentially long, half-life of chlorpyrifos in some soil types and on non-sun exposed surfaces (NRAAVC 2000)
- all the assumptions made in the Objective 1 evaluations, where scientifically appropriate
- Based on the outcomes of Objective 1 no spray applications except mosquito control uses were considered acceptable for the child accessible domestic and public space uses with application by back pack, low pressure hand wand or high pressure hand wand.

44. As stated above, the APVMA considers these assumptions to be reasonable.

[28] Exposure assessment and risk characterisation report, 2019, page 12.

45. The re-entry interval modelling was performed using US Environment Protection Agency (**EPA**) Occupational Pesticide Re-entry Exposure Calculator (**OPREC**), and did not include children (as that is covered by Scenario 3).

46. The results of the exposure assessments and risk characterisations conducted in respect of this scenario are set out in Table 3 of the Exposure assessment and risk characterisation report (2019), which is set out at **Annexure C** to this statement of reasons.

47. In each case, the Principal Toxicologist considered that the minimum re-entry intervals required for this purpose were impractical, unreliable and unenforceable given that these places were child-accessible public spaces and domestic/residential areas. As such, the use of minimum re-entry intervals were not regarded as a reliable risk management approach. The APVMA agrees with these conclusions.

(ix) Scenario 3: Non-professional uses of chlorpyrifos in child-accessible residential settings

48. The assumptions upon which the exposure assessment and risk characterisation conducted in respect of this scenario, stated in the Exposure assessment and risk characterisation report (2019), were as follows:[29]

- non-professional user exposure(s) were assumed to occur occasionally (minimum two chlorpyrifos applications to a maximum of three chlorpyrifos applications per year, with each exposure incident being toxicologically equivalent to an acute exposure incident with no more than one application per month). Accordingly the ARfD was regarded as the most appropriate human health based guidance value for assessment of mixing, loading and application. The relevant POD was 0.1 mg/kg bw/day which was the NOAEL for inhibition of erythrocyte cholinesterase in humans treated with a single oral dose of chlorpyrifos. A MOE of 10 x $10^{0.5}$ (rounded to 32) was applied to account for intra-species and other uncertainties (APVMA 2019)
- multiple re-entries into chlorpyrifos treated, child-accessible domestic/residential spaces were assumed to occur. As discussed above the most appropriate human health based guidance value for these circumstances was regarded as being the ADI
- where product labels only specified application to a small area (ie a garden, a rockery, or a potted plant) the evaluation assumed that the final application rate on a per unit area basis was ≥ 250 g a.c./ha
- apart from gloves, personal protective equipment was not regarded as a reliable risk management approach for non-professional residential users. This was due to concerns regarding compliance
- post-application re-entry intervals were not regarded as a reliable risk management approach for non-professional residential users due to concerns regarding compliance. Re-entry was assumed to occur on day 0 following application and drying of the applied material
- chlorpyrifos was only applied by people aged 16 years or older (regarded as adults)
- consistent with APVMA's current data on chlorpyrifos use in Australia, the evaluations also assumed that 100 per cent closed systems were not used during the mixing and loading processes
- the exposure assessments and risk characterisations assumed that there were no concurrent co-exposures to other anticholinesterase products (the effects of which are likely to be at least additive to those of chlorpyrifos due to their common mode of action)
- the exposure assessments and risk characterisations assumed that there will only one single use type per operator per occasional application instance.

49. As stated above, the APVMA considers these assumptions to be reasonable.

50. In the Exposure assessment and risk characterisation report (2019), the Principal Toxicologist stated that this scenario was modelled using the US EPA Occupational Pesticide Handler Exposure Calculator (**OPHEC**; version date: June 2018), with re-entry exposure modelling conducted using the APVMA Toddler on Turf model. The APVMA Toddler on Turf model is set out at **Annexure D** to this statement of reasons.[30]

51. Based on the outcomes of the exposure assessments and risk characterisations, in the Exposure assessment and risk characterisation report (2019) the Principal Toxicologist concluded that there are

[29] Exposure assessment and risk characterisation report, 2019, page 14.
[30] Exposure assessment and risk characterisation report, 2019, Appendix 4.

no acceptable residential (non-professional) chlorpyrifos uses, in most cases due to the risks associated with access to chlorpyrifos treated areas by children.[31]

52. The APVMA accepts the Principal Toxicologist's analysis, and the APVMA propose finding that the use of the products by non-professionals in child-accessible residential settings is likely to lead to exposure to chlorpyrifos at levels that exceed the acute reference dose.

(x) Overall conclusions of the Exposure assessments

53. The overall conclusions of the Exposure assessment and risk characterisation report (2019), were as follows:

Based on the criteria stipulated in section 5A of the *Agricultural and Veterinary Chemicals Code Act 1994*, the key overall outcome of the exposure assessments and risk characterisations (based on the data currently available to APVMA) is that there were no acceptable child-accessible domestic, residential and public space chlorpyrifos uses. Accordingly the following domestic, residential and public spaces uses of chlorpyrifos should be discontinued:

- container plants
- domestic areas
- domestic uses
- duboisia (in domestic and public space uses)
- exterior or outdoor areas of domestic buildings
- fences
- garden beds
- garden paths
- gardens
- in and around houses and domestic buildings
- macrocarpa hedges (in domestic and public space uses)
- potted ornamentals and other potted plants
- public places
- public service areas
- rockeries
- tennis courts
- uses on turf and/or lawns to which children have access
- mosquito adult/larvae control in vegetation.

The practical application of the above conclusions means that all home garden and domestic pest-control products containing ≤ 50 g/kg or L chlorpyrifos; and products with domestic and certain non-agricultural uses (that are mentioned above) containing > 50 g/kg or L chlorpyrifos are not supported.

The continued use of chlorpyrifos as a mosquito control agent in non-child accessible domestic, residential and public space water bodies is possible provided that children do not play in or around the treated body of water or swim in the treated body of water. Further exposure assessments and risk characterisations of child-accessible, chlorpyrifos-treated recreational water bodies are required to ensure adequate public health protection.

54. The APVMA accepts the Principal Toxicologist's overall conclusions in the Exposure assessment and risk characterisation report (2019), and the APVMA agrees that the following domestic, residential and public spaces uses of chlorpyrifos should be discontinued—container plants, domestic areas, domestic uses, duboisia (in domestic and public space uses), exterior or outdoor areas of domestic buildings, fences, garden beds, garden paths, gardens, in and around houses and domestic buildings, macrocarpa hedges (in domestic and public space uses), potted ornamentals and other potted plants,

[31] Exposure assessment and risk characterisation report, 2019, page 14.

public places, public service areas, rockeries, tennis courts, uses on turf and/or lawns to which children have access and mosquito adult/larvae control in vegetation.

55. The APVMA accepts that the practical application of the above findings of the Exposure report means that the continued use of chlorpyrifos as a mosquito control agent in non-child accessible domestic, residential and public space water bodies is possible provided that children do not play in or around the treated body of water or swim in the treated body of water.

(xi) Were the risks capable of being mitigated

56. In the Exposure assessment and risk characterisation report (2019), the Principal Toxicologist's risk assessment considered whether the risks could be alleviated by the use of risk mitigation strategies and concluded that they could not.[32] For the reasons set out in the following paragraphs, the APVMA agrees with that conclusion as the strategies are not reliable, practical or enforceable given children have access to the relevant areas.

57. For the sake of completeness, the APVMA wishes to note why the APVMA considers the Principal Toxicologist's assumptions in relation to the use of additional personal protective equipment (**PPE**), other than gloves, by non-professionals and re-entry intervals to be highly persuasive. At a theoretical level, mandating PPE (in addition to gloves) might reduce the exposure level. However, in the APVMA's view it is not reasonable, or realistic, to expect a high degree of compliance with any such requirement in the case of non-professional users of chemical products. It is appropriate for the APVMA to take into account the realism of any particular risk mitigation approach. In the present case, the Principal Toxicologist did not consider this to be a reliable risk mitigation measure for products used by non-professionals in residential settings, because of concerns regarding compliance, and the APVMA agrees with that view. For similar reasons, the APVMA agrees with the Principal Toxicologist's assumptions regarding re-entry intervals not being effective for risk mitigation purposes, particularly given that the relevant areas are accessible by children.

d) Conclusion

58. For the reasons set out above, on the material currently before the APVMA, the APVMA is not satisfied that the products are not, or would not be:

58.1 an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residue, for the purposes of paragraph 5A(1)(a) of the Code; and

58.2 likely to have an effect that is harmful to human beings, for the purposes of paragraph 5A(1)(b) of the Code.

Paragraph 5A(1)(c)

59. In relation to determining whether the products are not, or would not be, likely to have an unintended affect that is harmful to animals, plants or things or to the environment, the APVMA has had regard to expert advice commissioned from an external scientific reviewer by the APVMA's Scientific Assessment and Chemical Review team. The advice is contained in The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019).

60. The purpose of The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) was to supplement the APVMA's interim Environmental Assessment report published in September 2000, which identified

[32] Exposure assessment and risk characterisation report 2019, pages 14–15.

potential unacceptable risks to birds and aquatic organisms, particularly fish.[33] The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) therefore considered updated environmental data which have resulted in revised avian and aquatic toxicological end-points and revised risk assessment.

61. The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) sets out an assessment of the updated environmental data relevant to its consideration of the risks of the products to birds and aquatic organisms. That assessment demonstrates that birds are at the greatest risk. As a result of that assessment of the updated data, The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) states the following key revisions to avian toxicological end-points.

e) Avian acute dose

62. The interim Environmental Assessment set the acute avian oral lethal dose (LD_{50}) at 20 mg/kg bw.

63. The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) report reviewed the US EPA report for chlorpyrifos (**US EPA 1999**) and Solomon et al (2001), and the acute oral avian toxicity results reported in those reports.[34] Those results demonstrate that the most sensitive end-point was 8.5 mg/kg (geometric mean) for the common grackle, and The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) found that the geometric mean avian LD_{50} was 28.9 mg/kg bw. The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) advised that the geometric mean approach in assessing risks is the most appropriate approach to adopt, and was considered scientifically valid, based on an assessment by the European Union Joint Working Group for the European Food Safety Authority.[35] The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) therefore applied the geometric mean avian LD_{50} of 28.9 mg/kg bw and applied that as the acute avian end-point in the risk assessment.[36] Having reviewed The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019), the APVMA agrees with this analysis and propose finding that the acute avian end-point should be amended from 20 mg/kg bw to 28.9 mg/kg bw.

f) Avian chronic dose

64. The interim Environmental Assessment did not identify a no observed effect concentration (**NOEC**) or perform a chronic avian risk assessment.

65. The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) reviewed the US EPA 1999 report, with the toxicity results set out on page 18 of The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019). It is noted

[33] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 7.

[34] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019), pages 13–17; US EPA, 1999, *Reregistration Eligibility Science Chapter for Chlorpyrifos, Fate and Environmental Risk Assessment Chapter,* October 1999 (Revision); Solomon, KR, Giesy, JP, Kendall, Best, LB, Coats JR, Dixon KR, Hooper, MJ, Kenaga EE & McMurry ST, 2001, Chlorpyrifos: Ecotoxicological risk assessment for birds and mammals in corn agroecosystems, *Human and Ecological risk assessment: An international journal*, 7:3, pp. 497–632.

[35] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 16.

[36] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 17.

that both the European Union (2005) and the US EPA 1999 used a NOEC of 25 mg/kg diet as their chronic avian end-point, and that this is consistent with other studies.[37]

66. The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) noted that Australia does not have standard indicator species for different cropping situations, but that the native pacific black duck is closely related and may interbreed with the mallard, and therefore the use of the mallard duck results are relevant.[38] The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) therefore affirmed the chronic avian dietary NOEC 25 mg/kg diet as the most appropriate end-point and found that this relates to a daily dose of 2.88 mg/kg bw/d, which was applied in the risk assessment.[39] This was consistent with the NOEC reported by Hakin (1990a) and Fink et al, (1978a).[40] Having reviewed The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019), the APVMA agrees with this analysis and propose finding that the chronic avian dietary end-point be set at 25 mg/kg, with a daily dietary dose of 2.88 mg/kg bw/d.

g) Environmental risk assessments

67. Applying the revised toxicological end-points, the Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) sets out the findings of the risk assessments conducted for relevant organisms, including avian, mammalian and aquatic species. Those assessments demonstrated that the highest risk was through acute exposure to birds.

68. In relation to the avian risk assessment, the Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019) contains the following findings:

68.1 Birds have been reported to consume chlorpyrifos granules directly in the home gardens as well as ingest insects poisoned by chlorpyrifos uses in urban situations resulting in adverse effects.[41]

68.2 Analysis of toxicity data, higher tier avian assessment, and a range of field data, demonstrated that single application rates below 850 g ac/ha are within acceptable limits and the possibility of avian field mortality is unlikely.[42]

68.3 Many granular ant control products do not provide an actual rate in terms of quantity per area (g/m^2), so there is potential for concentrated amounts of granules to be applied in home garden situations.[43] When rates are provided, the standard application rate for chlorpyrifos granular

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[37] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 18; EC, 2005, Final Review report for the active substance chlorpyrifos, SANCO/3059/99–rev. 1.5, 3 June 2005, European Commission, available at ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.ViewReview&id=138.

[38] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 19.

[39] Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 19.

[40] Hakin, B, 1990, *The Effect of Dietary Inclusion of Chlorpyrifos on Reproduction in the Mallard Duck*, Performed by Huntingdon Research Centre Ltd, Huntingdon, Cambridgeshire, UK for Makhteshim-Agan (America) Inc. (Unpublished report). US EPA - MRID Number: 42144901; Fink, R, et al, 1978a, *The effect of chlorpyrifos during a one-generation reproduction study on the mallard*, Project Number: 103-178, Prepared by Wildlife International for The Dow Chemical Company, Midland, MI, USA (Unpublished report). US EPA – MRID Number: 00046952.

[41] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 13.

[42] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 34.

[43] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.

products are high (20 g ac/100 m^2 equivalent to 2000 g ac/ha) and these products are mostly not incorporated into the soil.[44] Assuming granules are spread evenly at a rate of 20 g ac/100 m^2, this equates to approximately 7 LD_{50} s/m^2.[45] For the acute assessment, potential risk is identified where > 1 LD_{50} s/m^2 is calculated (10 LD_{50} s/m^2 with a level of concern = 0.1).[46] The standard application rate for chlorpyrifos granular products are high (20 g ac/100 m^2, equivalent to 2000 g ac/ha) therefore exceeds the upper rate identified for an acceptable risk to birds (850 g ac/ha).[47]

68.4 Home garden spray products tend to contain chlorpyrifos in low concentrations (50 g/L or less) with use on lawns, garden beds and in and around the home at rates essentially the same as those for the home garden granular products.[48] Small pack size is a limiting factor to the coverage that the products can achieve.[49] For those products with stated application rates, based on pack sizes, coverage could range from 50 m^2 to 750 m^2 and half of the products would only have sufficient formulation for approximately 170 m^2 or less.[50] Nonetheless, there are several products that do not prescribe application rates, and some have larger pack sizes (2L).[51] Further, the treatment rates when these products are applied is up to 20 g ac/50 m^2 (4000 g ac/ha).[52] Accordingly, this use also exceeds the upper rate identified for an acceptable risk to birds (850 g ac/ha).[53]

69. Having reviewed The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019), the APVMA accepts the analysis contained in the report. On the basis of The Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019), the APVMA accepts the recommendations made regarding the avian toxicological end-points and revised risk assessment. In particular, the APVMA propose finding that:

69.1 single application rates that exceed 850 g ac/ha pose an unacceptable risk to birds;

69.2 the home garden/urban use granular product class poses an unacceptable risk to birds, as the standard application rate exceeds 850 g ac/ha; and

69.3 the home garden/urban use spray product class with usage rates > 850 g ac/ha poses an unacceptable risk to birds.

70. For these reasons, on the material currently before the APVMA, the APVMA is not satisfied that the products are not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment for the purposes of paragraph 5A(1)(c) of the Code.

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[44] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[45] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[46] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[47] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[48] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[49] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[50] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[51] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[52] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.
[53] Reconsideration of chlorpyrifos—Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses, 2019, page 28.

Conclusion on the safety criteria

71. For the reasons set out above, the APVMA propose finding that none of paragraphs 5A(1)(a), (b) or (c) are satisfied in respect of the products. Accordingly, the APVMA propose finding that the products listed in **Annexure A** do not meet any of the safety criteria set out in subsection 5A(1) of the Code.

Conclusion on whether the products meet the safety criteria

72. For the reasons set out above, on the material currently before the APVMA, the APVMA propose finding that the products do not satisfy the requirements of paragraph 34(1)(b) of the Code in order to affirm the registration of the products. As all of the safety, trade and efficacy criteria must be satisfied in order to meet the requirements of paragraph 34(1)(b), that is, the criteria are cumulative, and the APVMA propose finding that the products do not meet the safety criteria, it is not necessary for the APVMA to make any findings in relation to the other criteria.

Issue 2—can the relevant particulars or conditions of the registration be varied in such a way to allow registration to be affirmed? [paragraph 34A(1)(b)]

73. As the APVMA propose finding that the requirements of subsection 34(1) of the Code are not met in relation to the products, the APVMA must propose varying the relevant particulars or conditions of the registration if they can be varied in such a way as to allow registration to be affirmed. However varying relevant particulars and/or conditions of registration could not make the products meet the required safety criteria.

74. On the material currently before the APVMA, the APVMA is not satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed. Accordingly, the APVMA does not propose varying the relevant particulars or conditions of the registration under subsection 34A(1) of the Code.

Issue 3—proposed cancellation of the products [subsection 34AA(1)]

75. As the APVMA is not satisfied, on the material currently before the APVMA, that the products meet the requirements of paragraph 34(1)(b) of the Code or that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed under subsection 34A(1) of the Code, the APVMA propose not affirming the registration of the products. In those circumstances, subsection 34AA(1) of the Code will require the registration of the products to be suspended or cancelled.

76. In the circumstances, the APVMA propose cancelling the registration of the products.

ANNEXURE A—CHLORPYRIFOS HOME GARDEN AND DOMESTIC PEST-CONTROL PRODUCT REGISTRATIONS PROPOSED FOR CANCELLATION

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
33198	Heiniger Banant Granules	Heiniger Australia Pty Ltd	33198/0709 33198/0402 33198/1100
39222	David Grays Antex Granules	David Gray & Co. Pty Limited	39222/1000
45227	Surefire Antout Granular Insecticide	PCT Holdings Pty Ltd	45227/115365 45227/0501
45449	Brunnings Lawn Grub Destroyer	Brunnings Garden Products Pty Ltd	45449/0502 45449/0102
47528	Heiniger Lawn Beetle Blitz Insecticide	Heiniger Australia Pty Ltd	47528/1208 47528/1200
49315	Richgro Garden Products Lawn Beetle and Grub Killer	A. Richards Pty Ltd	49315/0206
49666	Barmac Chlorpyrifos G Granular Insecticide	Amgrow Pty Ltd	49666/0402
51769	Garrards Ant Killer 50	Garrards Pty Ltd	51769/0402
52167	Munns Lawn Grubs, Lawn Beetle Grubs & Slater Killer With Long Life Organically Advanced Weta-Lawn	Duluxgroup (Australia) Pty Ltd	52167/58862
52564	David Grays Antex 50 Granular Professional Insecticide	David Gray & Co. Pty Limited	52564/0401
55444	Searles Ant Kill 50 Granules	J C & A T Searle Pty Ltd	55444/0206 55444/0602
55961	Searles Lawn Grub Killer Granules	J C & A T Searle Pty Ltd	55961/0206 55961/0702
56209	Superway Grub, Ant And Pest Controller	Superway Garden Ag & Pest Products Pty Ltd	56209/0509 56209/0103
56495	Richgro Home Garden Ant Killer	A. Richards Pty Ltd	56495/0206 56495/0304
56616	Amgrow Patrol Lawn Grub & Beetle Killer Granules	Amgrow Pty Ltd	56616/57257 56616/0303
57758	David Grays Lawn Beetle & Grub Killer Insecticide	David Gray & Co. Pty Limited	57758/0903
58188	Surefire Lawn Grub,Ant and Outdoor Pest Insecticide	PCT Holdings Pty Ltd	58188/1103

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
58286	Richgro Ant Killer	A. Richards Pty Ltd	58286/0206 58286/0304
58287	Richgro Slater Killer	A. Richards Pty Ltd	58287/0506 58287/0206 58287/1004
58294	Richgro Lawn Beetle Killer	A. Richards Pty Ltd	58294/0206 58294/0304
58479	Grass Gard Lawn Beetle & Grub Spray	Heiniger Australia Pty Ltd	58479/1208 58479/0205
61354	Searles Lawn Grub Killer Hose On	J C & A T Searle Pty Ltd	61354/1006
61533	Amgrow Sir Walter Buffalo Lawn Pest Control	Amgrow Pty Ltd	61533/0808 61533/1206
64936	Amgrow Patrol Fix Ant	Amgrow Pty Ltd	64936/49635
67248	Searles Ant Kill 50	J C & A T Searle Pty Ltd	67248/55593
67249	Searles Lawn Grub Killer	J C & A T Searle Pty Ltd	67249/55594
83025	Delfos 5G Insecticide	Industrial Quimica Key S.A.	83025/107339

ANNEXURE B—ACCEPTABLE PROFESSIONAL PUBLIC SPACE USES OF CLORPYRIFOS BASED ON MIXING, LOADING AND APPLICATION EXPOSURE MODELLING USING US EPA OPHEC

Crop/use	Application method	Application rate	Work rate	MOE†	Comments
Child-accessible domestic and child-accessible public space uses (professional use) Container plants Domestic areas Domestic uses Duboisia (in domestic and public space uses) Exterior or outdoor areas of domestic buildings Fences Garden beds Garden paths Gardens In and around houses and domestic buildings Macrocarpa hedges (in domestic and public space uses) Potted ornamentals and other potted plants Public places Public service areas Rockeries Tennis courts Uses on turf and/or lawns to which children have access	Push type spreader (granules)	0.1 g a.c./m^2	2000 m^2/d	526	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or coveralls buttoned at the wrist and neck, socks and boots)
	Push type spreader (granules)	0.2 g a.c./m^2	2000 m^2/d	263	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or coveralls buttoned at the wrist and neck, socks and boots)
	Push type spreader (granules)	0.4 g a.c./m^2	2000 m^2/d	132	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or coveralls buttoned at the wrist and neck, socks and boots)
	Mechanical (open cab, tractor drawn) spreader (granules)	0.1 g a.c./m^2	5 ha/d	326	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or coveralls buttoned at the wrist and neck, socks and boots)

Crop/use	Application method	Application rate	Work rate	MOE† ֍	Comments
	Mechanical (open cab, tractor drawn) spreader (granules)	0.2 g a.c./m^2	5 ha/d	163	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or coveralls buttoned at the wrist and neck, socks and boots)
Professional use products Mosquito adult/larvae control in water bodies	High pressure hand wand	10 g a.c./100 kL water body	20 kL water body/d	>1000	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or coveralls buttoned at the wrist and neck, socks and boots)
	Low pressure hand wand	10 g a.c./100 kL water body	20 kL water body/d	123	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or coveralls buttoned at the wrist and neck, socks and boots)
	Backpack	10 g a.c./100 kL	50 kL water body/d	591	**Required personal protective equipment:** Chemical resistant gloves and a double layer of chemical resistant clothing
Professional use products Mosquito adult/larvae control in vegetation	High pressure hand wand	15 g a.c./ha	5 ha/d	266	**Required personal protective equipment:** Long sleeved shirt buttoned at the neck and wrist, long pants, socks and boots (or

Crop/use	Application method	Application rate	Work rate	MOE† ֍	Comments
					coveralls buttoned at the wrist and neck, socks and boots)
	Low pressure hand wand	15 g a.c./ha	5 ha/d	>1000	**Required personal protective equipment:** Chemical resistant gloves PLUS long sleeved shirt buttoned at the wrist and collar plus long pants plus boots and socks (or coveralls buttoned at the neck and wrist plus boots)

** Acceptable MOE ≥ 100; POD in rats is 0.1 mg/kg bw/day which was the NOAEL for inhibition of blood cholinesterases.*

† Assumes a single professional operator mixes, loads and applies the product.

֍ The overall MOE accounts for both dermal and inhalation exposures.

ANNEXURE C—RE-ENTRY RISK CHARACTERISATION BASED ON OPREC

Crop/use	Minimum re-entry interval required to achieve MOE > 100	Comments
Child-accessible domestic and child-accessible public space uses (professional use) Container plants Domestic areas Domestic uses Duboisia (in domestic and public space uses) Exterior or outdoor areas of domestic buildings Fences Garden beds Garden paths Gardens In and around houses and domestic buildings Macrocarpa hedges (in domestic and public space uses) Potted ornamentals and other potted plants Public places Public service areas Rockeries Tennis courts Uses on turf and/or lawns to which children have access	2–34 days depending on plant height, plant foliage density and activity undertaken.	A re-entry requirement in child accessible spaces is regarded as impractical, unreliable and unenforceable.
Professional use products Mosquito adult/larvae control in vegetation	0 days	The use is considered to be practical based on re-entry criteria. *Note: re-entry exposures to children are not acceptable based on APVMA Toddler on Turf (MOE < 100).*

ANNEXURE D—APVMA TODDLER ON TURF MODEL

In the absence of post-application residue and/or exposure studies, the following calculations have been made for exposure to children playing on treated lawn areas, using the Toddler on Turf algorithm. Exposure estimations have been performed for infants (< two year old) and toddlers (two to three year old), using the formula below:

$$E_{(Total/dayN)} = \left[\underbrace{\frac{[AR \times (1\text{-}DRn)^{dayN}] \times [DepR \times Ac] \times TC \times ET \times DA}{BW}}_{\text{Dermal}} + \underbrace{\frac{[AR \times (1\text{-}DRn)^{dayN}] \times [DepR \times Ac] \times SAo \times FQ \times ET \times B}{BW}}_{\text{Oral}} \right]$$

Where:

AR (Application rate); **B** (oral bioavailability): The oral bioavailability data for the active constituent chlorpyrifos is a factor of 0.77 (ie 77 per cent gastrointestinal absorption).

BW (Bodyweight): One to two year olds = 11 kg, two to three year olds = 15 kg; **DA** (product-specific dermal absorption factor [fraction]): 10 per cent for diluted product (ie 0.10).

DepR (Deposited Residue [fraction]) *and* **Ac** (Accessibility factor [fraction])—together, these factors constitute a transferable residue factor. The default for the accessibility of organics on surfaces is 100 per cent (1.0), and 0.01 per cent (0.0001) for inorganics. For turf, a transferable residue factor (**DepR x Ac**) of five per cent was applied. The default is five per cent (0.05) for all formulation and application types.

DRn (Nominal dissipation/ degradation rate per day) expressed as [fraction]): in the absence of product-specific data to estimate a data-derived nominal dissipation rate, the default 'actual' product-specific dissipation/degradation rate for residues on surfaces (indoors and outdoors) is only equal to the levels lost from transfer to occupants (ie transferred to skin). **For turf**, the default nominal value for dissipation/degradation rate per day is 10 per cent (0.1). This value has been maintained as the default in the absence of additional data. As this default is a conservative factor based on the physical process of blade-growth and subsequent mowing and/or blade turnover, selecting longer dissipation rates (eg due to long environmental half-lives) is inappropriate for estimating post-application exposures to residues on turf. In the cases where a long environmental half-live for an active constituent (ideally from studies where it was a component of the formulation) has been identified, estimating repeated exposure from soil ingestion of 50 mg soil/day.

ET (Exposure time/duration of mouthing per day): For time spent playing on turf, the default mean values are 1.1h [95th percentile of two hours] and 1h [95th percentile of two hours] for infants (< two) and toddlers (two to three), respectively; **FQ** (Mouthing Frequency): the default mouthing frequency values in outdoor settings are 14/5 contacts per hour for < two/two to three-year olds, respectively.

SAo (Surface area potentially exposed from mouthing activities): The value of 19 cm^2 per event is used for area mouthed per mouthing event.

TC (Transfer Coefficient): for turf the default dermal TC values for children playing on treated turf are:

- two to three-year olds = 60,000 cm^2/h
- one to two-year olds = 49,000 cm^2/h.

Values for two to three-year olds are estimated from extrapolating the value to < two-year olds based on a 1.23-fold lower exposed surface area.

Dermal NOAEL: Nil (No suitable study available); Oral NOAEL: A NOAEL of 0.1 mg/kg bw/d was selected from a rat study. A MOE of exposure was regarded as acceptable. A dermal absorption factor of three per cent (0.03) was used for route-to-route extrapolation.