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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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PREAMBLE

On 24 June 2019 APVMA notified the registrants and holders of APVMA's proposed regulatory decision, based on sections 41(2) and 34P of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Cth) (Code)*. The proposed decision was to suspend label approvals of certain chlorpyrifos products with domestic, agricultural and certain non-agricultural uses (shown in Annex A) for a period of 12 months. The reason for this proposed decision was that these labels did not meet the labelling criteria as defined in section 5D of the Code. The APVMA invited submissions on its proposed regulatory decision until 22 July 2019.

The APVMA has had regard to all submissions made in response to its invitation under section 34P of the Code and has decided to suspend the label approvals of certain chlorpyrifos products with domestic, agricultural and certain non-agricultural uses (shown in Annex E) on the basis that those labels do not meet the labelling criteria. The period of suspension is 12 months, from 26 July 2019 through 26 July 2020.

Instructions for possession, custody, and use of products whose label approvals are suspended can be found in [Permit Number PER88402](#)¹. The supply of suspended products is not acceptable under this permit.

The consequences under the Code of failing to comply with these instructions during the 12 month suspension period in respect of possessing, having custody of or otherwise dealing with the products whose label approvals are suspended are:

- a. commission of an offence under section 45C(5) of the Code; and
- b. subject to civil penalty proceedings under section 45C(7) of the Code.

¹ <http://permits.apvma.gov.au/PER88402.PDF>

REGULATORY DECISION TO SUSPEND LABEL APPROVALS OF CHLORPYRIFOS PRODUCTS WITH CERTAIN USES

1. The APVMA has suspended the label approvals for the chemical products (**products**) listed in the table in **Annexure A** under section 41(2) of the Agricultural and Veterinary Chemicals Code in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994 (Cth)* (**Code**) for a period of 12 months effective 26 July 2019 (**the decision**).
2. This document sets out the APVMA reasons for the decision, as required by paragraph 34P(1)(b) of the Code.

Legal Framework

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

RECONSIDERATION OF LABEL APPROVAL

4. The Code provides, under section 31, that the APVMA may reconsider, relevantly, the approval of a label for containers of a chemical product. Reconsideration process is to be undertaken in accordance with the provisions of Division 4 of Part 2 of the Code.
 5. This reconsideration process does not preclude the APVMA from taking action in regard to the approval of a label for containers for a chemical product prior to the conclusion of the reconsideration process.
 6. In particular:
 - 6.1 subsection 41(2) of the Code provides that the APVMA may suspend or cancel the approval of a label for containers for a chemical product if it appears to the APVMA that the label may not meet the labelling criteria or may not comply with any requirements prescribed by the regulations.
 7. Subsection 41(2) of the Code provides that the APVMA may suspend or cancel the approval of a label for containers for a chemical product if it appears to the APVMA that the label may not meet the labelling criteria or may not comply with any requirements prescribed by the regulations.
 8. Section 43 of the Code requires that, if the APVMA suspends an approval or registration, it must be for a stated period, with the approval or registration taken for the purposes of the Code (other than sections 74 and 75) not to be in force during that period of suspension.
 9. Section 34P of the Code requires the APVMA to give notice of a proposed suspension or cancellation under Division 5 of Part 2 to be given to the holder of the registration. In particular, the APVMA must notify the holder that it proposes to suspend or cancel the registration, set out the reasons for the proposed suspension or cancellation, and invite the holder to make, within a reasonable period, submissions in relation to the proposed suspension or cancellation.
 10. Section 35 of the Code also requires the APVMA to give notice of the proposed suspension or cancellation to be given to each co-ordinator for a jurisdiction.
 11. If the APVMA suspends approval of a label, it must give notice in accordance with the provisions in Division 5 of Part 2 of the Code.
-

Material on which the APVMA findings are based

12. In making this decision the APVMA had regard to:
- 12.1 advice from the Chemical Review section of the APVMA as to the relevant particulars of the products, in particular the APVMA product registration number, the distinguishing name of the chemical product, registration holder and label approval number(s) as provided in **Annexure A**.
 - 12.2 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 as set out in the report entitled *Reconsideration of chlorpyrifos: Toxicology update, 2019*;
 - 12.3 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, as set out in a report entitled *Reconsideration of chlorpyrifos: Residential exposure and public space use exposure assessment and risk characterisation update, 2019*;
 - 12.4 advice commissioned by the APVMA's 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 1 – Home garden, domestic and certain non-agricultural uses, 2019*;
 - 12.5 relevant provisions of the Code;
 - 12.6 APVMA's policy on Worker health and safety risk assessments;²
 - 12.7 information given in response to 78 notices given under subsection 32(1);
 - 12.8 submissions made to the APVMA in response to an invitation under paragraph 32(2A)(b); and
 - 12.9 information given to the APVMA in response to two notices given under section 33.
13. 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.³ The APVMA is not aware of any other information that falls within paragraph 34(3)(a) of the Code that requires consideration.
14. Based on the advice the APVMA has had regard to, the APVMA makes the following findings of fact which are material to the decision:
- 14.1 chlorpyrifos is hazardous to mammals (including human beings) – that is, it has the *potential* to cause harm;
 - 14.2 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;
 - 14.3 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;

² APVMA, "[Worker Health and Safety Risk Assessments undertaken by the APVMA](#)" (12 June 2018) accessed 1 May 2019.

³ Code, paragraph 34(3)(a)(vi).

- 14.4 the acceptable daily intake (**ADI**) for chlorpyrifos is 0.001 mg/kg bw/day (1 µ/kg bw/day);
 - 14.5 the acute reference dose for chlorpyrifos is 0.03 mg/kg bw;
 - 14.6 chlorpyrifos exposure reasonably expected in connection with non-professional residential use of the products will likely exceed the acute reference dose;
 - 14.7 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;
 - 14.8 the use of the products by in a residential setting is likely to have an effect that is harmful to human beings;
 - 14.9 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;
 - 14.10 the chronic avian dietary no observed effect concentration for chlorpyrifos is 25 mg/kg;
 - 14.11 the acute avian oral lethal dose (LD₅₀) is 28.9 mg/kg bw;
 - 14.12 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;
 - 14.13 granular chlorpyrifos products used in a residential setting are prone to being applied at application rates in excess of 850 g ac/ha; and
 - 14.14 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 labels meet the labelling criteria? (s41(2))

15. Subsection 41(2) of the Code provides that the APVMA may suspend or cancel the approval for a label for containers for a chemical product if it appears that the label may not meet the labelling criteria.
16. The definition of meets the labelling criteria is set out in section 5D of the Act:
- 1) A label for containers for a chemical product meets the labelling criteria if the label contains adequate instructions relating to such of the following as are appropriate:
 - (a) the circumstances in which the product should be used;
 - (b) how the product should be used;
 - (c) the times when the product should be used;
 - (d) the frequency of the use of the product;
 - (e) the withholding period after the use of the product;
 - (f) the re-entry period after the use of the product;
 - (g) the disposal of the product when it is no longer required;
 - (h) the disposal of containers of the product;
 - (i) the safe handling of the product and first aid in the event of an accident caused by the handling of the product;
 - (j) any matters prescribed by the regulations.
 - 2) For the purposes of being satisfied as to whether a label meets the labelling criteria, the APVMA must have regard to the following:
 - (a) any conditions to which its approval is, or would be, subject;
 - (b) any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label;
 - (c) whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).
17. 'Adequate', in relation to instructions on a label, 'means adequate to ensure, as far as reasonably practicable, that the product meets the safety criteria and the trade criteria'.⁴
18. Regulation 8AE of the Agvet Code Regulations sets out matters prescribed under paragraph 5D(1)(i) of the Code.
- (1) For paragraph 5D(1)(j) of the Code, the following are prescribed matters:
 - (a) for a chemical product that is a veterinary chemical product—the duration of any treatment using the product;
 - (b) the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia;
 - (c) the appropriate signal words (if any) required by the current Poisons Standard;

⁴ Code, section 3 (Definitions – *adequate*).

- (d) for a chemical product that is a date-controlled chemical product—the storage of containers for the product;
 - (e) any other matter determined by the APVMA CEO under subregulation (2).
- (2) For paragraph 6(2)(c) of the Act, the APVMA CEO may determine matters in relation to which a label must contain adequate instructions.

HUMAN HEALTH ASSESSMENTS

19. 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 (i.e., 'high dose chlorpyrifos exposure') results in adverse effects; particularly adverse effects on neurodevelopment and neurobehavioural developmental.⁵

Acceptable daily intake: Identifying an appropriate point of departure

20. APVMA notes 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.⁶ 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 179 in human volunteers (Coulston and Golberg, 1972)*.⁷ 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.
21. 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 the *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.⁸ 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.⁹
22. In the *Reconsideration of chlorpyrifos: Toxicology update (2019)*, the Principal Toxicologist recommend 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 2010¹⁰ and Marty *et al.* in 2012.¹¹ 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).¹² The *Reconsideration of chlorpyrifos: Toxicology update (2019)* notes that this point of departure is also supported by toxicological thresholds in other studies that have

⁵ Reconsideration of chlorpyrifos: Toxicology update (2019), pages 9-10.

⁶ Code, s 5A(3)(b)(i).

⁷ 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*.

⁸ Reconsideration of chlorpyrifos: Toxicology update (2019), page 16.

⁹ Reconsideration of chlorpyrifos: Toxicology update (2019), page 20.

¹⁰ 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

¹¹ 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

¹² Reconsideration of chlorpyrifos: Toxicology update (2019), page 20

been evaluated by the APVMA.¹³ 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.

Uncertainty factors

23. 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.¹⁴ The Principal Toxicologist further recommended that an uncertainty factor of 10 be applied to account for inter-species variations.¹⁵ Thus the total recommended uncertainty factor to be applied is 100.¹⁶ The APVMA is advised, and the APVMA accepts, that the application of such uncertainty factors is consistent with established approaches to regulatory toxicology.

New acceptable daily intake: identifying an appropriate point of departure

24. 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).¹⁷
25. On the basis of this advice, the APVMA find that 0.001 mg/kg bw/day (1 µ/kg bw/day) is the new ADI for chlorpyrifos.
26. 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).¹⁸ 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).¹⁹
27. 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).²⁰ 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)*.
28. On this basis, the APVMA accepts the Principal Toxicologist recommendation that the current human acute, single dose NOEL for inhibition of plasma cholinesterase of 0.1 mg/kg bw derived from Kisicki (1999) be retained. This forms the point of departure for the calculation of the acute reference dose.

Uncertainty factors

29. 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.²¹ 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

¹³ Reconsideration of chlorpyrifos: Toxicology update (2019), page 20.

¹⁴ Reconsideration of chlorpyrifos: Toxicology update (2019), page 20.

¹⁵ Reconsideration of chlorpyrifos: Toxicology update (2019), page 20.

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 7.

¹⁹ 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*.

²⁰ Reconsideration of chlorpyrifos: Toxicology update (2019), page 19.

²¹ Reconsideration of chlorpyrifos: Toxicology update (2019), page 22.

remaining uncertainties.²² The APVMA accepts these recommendations, and therefore find that the total uncertainty factor to be applied is $10 \times 10^{0.5}$.

New acute reference dose

In the *Reconsideration of chlorpyrifos: Toxicology update (2019)*, the Principal Toxicologist proposes 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 finds that 0.03 mg/kg bw (30 µg/kg bw) is the new acute reference dose.

Exposure assessment

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 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.

30. Exposure assessments and risk characterisations were conducted in respect of three relevant scenarios:
- 30.1 professional applicators who mix, load and apply chlorpyrifos for use in child-accessible public spaces and domestic/residential areas;
 - 30.2 professional applicators who re-enter chlorpyrifos-treated, child-accessible public spaces and domestic/residential areas; and
 - 30.3 non-professional uses of chlorpyrifos in child-accessible residential settings.
31. 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.
32. The APVMA has also had regard to the particular models used in the risk assessments. The APVMA accept these as being the most relevant and robust models available for this purpose.

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

33. 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:²³
- a) professional trained applicators mixed, loaded and applied chlorpyrifos
 - b) 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
 - c) professional applicators were assumed to be trained, competent, experienced and compliant users of personal protective equipment
 - d) professional operators were assumed to be trained in, and were competent, experienced and compliant users of relevant application techniques and equipment
 - e) professional applicators were assumed to have a high degree of competence regarding the interpretation of label requirements

²² Reconsideration of chlorpyrifos: Toxicology update (2019), page 22.

²³ Exposure assessment and risk characterisation report (2019), pages 8-9.

- f) 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
- g) the assessments assumed that amongst professional applicators there would be a high level of compliance with label directed mandatory minimum re-entry intervals
- h) 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 i.e., a single operator mixes, loads and applies the pesticide during product use
- i) 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 (e.g., 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
- j) 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
- k) 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
- l) 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.
- m) Work rates are based on label information and information contained in NOHSC 2001, Compendium of Farming Practices, National Occupational Health & Safety Commission, Canberra.

34. As stated above, the APVMA considers these assumptions to be reasonable.
35. 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)*.
36. 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 as **Annexure B** to this statement of reasons.
37. 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)*.
38. The APVMA therefore find 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 find 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.

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

39. 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:²⁴
- a) a maximum acceptable re-entry interval of one day was applied to ensure drying of the applied material
 - b) 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
 - c) re-entry exposure was assumed to be via dermal exposure. Inhalation exposures under these circumstances were regarded as toxicologically negligible
 - d) only the most exposure-intensive activities for each situation were evaluated (worst case scenario)
 - e) mandatory minimum re-entry intervals for child-accessible public spaces were not regarded as a reliable risk management approach

²⁴ Exposure assessment and risk characterisation report (2019), page 12.

- f) 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)
 - g) all the assumptions made in the Objective 1 evaluations, where scientifically appropriate.
 - h) 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 backpack, low pressure hand wand or high pressure hand wand.
40. As stated above, the APVMA considers these assumptions to be reasonable.
41. 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).
42. 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.
43. 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.

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

44. 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:²⁵
- a) 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 $10 \times 10^{0.5}$ (rounded to 32) was applied to account for intra-species and other uncertainties (APVMA 2019)
 - b) 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
 - c) 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
 - d) 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
 - e) 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
 - f) chlorpyrifos was only applied by people aged 16 years or older (regarded as adults)
 - g) 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
 - h) 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)
 - i) the exposure assessments and risk characterisations assumed that there will only one single use type per operator per occasional application instance.
45. As stated above, the APVMA considers these assumptions to be reasonable.
46. 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

²⁵ Exposure assessment and risk characterisation report (2019), pages 14.

Toddler on Turf model. The APVMA Toddler on Turf model is set out at **Annexure D** to this statement of reasons.²⁶

47. 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 no acceptable residential (non-professional) chlorpyrifos uses, in most cases due to the risks associated with access to chlorpyrifos treated areas by children.²⁷
48. The APVMA accepts the Principal Toxicologist's analysis, and the APVMA find 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.

Overall conclusions of the exposure assessments

49. 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.

50. 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,

²⁶ Exposure assessment and risk characterisation report (2019), Appendix 4.

²⁷ Exposure assessment and risk characterisation report (2019), page 14.

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 and mosquito adult/larvae control in vegetation.

51. The APVMA also accepts that the practical application of the above findings of the *Exposure assessment and risk characterisation report (2019)* 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.

Were the risks capable of being mitigated?

52. 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.²⁸ 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.
53. 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.

Environmental assessment

54. 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 Risk Assessment Capability section. The advice is contained in the *Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019)*.
55. 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 potential unacceptable risks to birds and aquatic organisms, particularly fish.²⁹ 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.
56. 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

²⁸ Exposure assessment and risk characterisation report (2019), page 14 and 15.

²⁹ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 7.

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.

Avian acute dose

57. The interim *Environmental Assessment* set the acute avian oral lethal dose (LD₅₀) at 20 mg/kg bw.
58. The *Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019)* 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.³⁰ 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 LD₅₀ 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.³¹ 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 LD₅₀ of 28.9 mg/kg bw and applied that as the acute avian end-point in the risk assessment.³² 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 find that the acute avian end-point should be amended from 20 mg/kg bw to 28.9 mg/kg bw.

Avian chronic dose

59. The interim *Environmental Assessment* did not identify a no observed effect concentration (NOEC) or perform a chronic avian risk assessment.
60. 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 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.³³
61. 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

³⁰ *Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019)*, page 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.

³¹ *Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019)*, page 16.

³² *Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019)*, page 17.

³³ *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.

and may interbreed with the mallard, and therefore the use of the mallard duck results are relevant.³⁴ 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.³⁵ This was consistent with the NOEC reported by Hakin (1990a) and Fink (1978a).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 find that the chronic avian dietary end-point is set at 25 mg/kg, with a daily dose of 2.88 mg/kg bw/d.

Environmental risk assessments

62. Applying the revised toxicological end-points, the Environmental Report 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.
63. In relation to the avian risk assessment, the Environmental Report contains the following findings:
 - 63.1 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.³⁷
 - 63.2 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.³⁸
 - 63.3 Many granular ant control products do not provide an actual rate in terms of quantity per area (g/m²), so there is potential for concentrated amounts of granules to be applied in home garden situations.³⁹ When rates are provided, the standard application rate for chlorpyrifos granular products are high (20 g ac/100 m² equivalent to 2000 g ac/ha) and these products are mostly not incorporated into the soil.⁴⁰ Assuming granules are spread evenly at a rate of 20 g ac/100 m², this equates to approximately 7 LD₅₀ s/m².⁴¹ For the acute assessment, potential risk is identified where > 1 LD₅₀ s/m² is calculated (10 LD₅₀ s/m² with a level of concern = 0.1).⁴² The standard application rate for chlorpyrifos granular products are high (20 g ac/100 m², equivalent to 2000 g ac/ha) therefore exceeds the upper rate identified for an acceptable risk to birds (850 g ac/ha).⁴³

³⁴ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 19.

³⁵ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 19.

³⁶ 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

³⁷ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 13.

³⁸ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 34.

³⁹ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 28.

⁴⁰ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 28.

⁴¹ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 28.

⁴² Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 28.

⁴³ Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019), page 28.

- 63.4 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.⁴⁴ Small pack size is a limiting factor to the coverage that the products can achieve.⁴⁵ For those products with stated application rates, based on pack sizes, coverage could range from 50 m² to 750 m² and half of the products would only have sufficient formulation for approximately 170 m² or less.⁴⁶ Nonetheless, there are several products that do not prescribe application rates, and some have larger pack sizes (2L).⁴⁷ Further, the treatment rates when these products are applied is up to 20 g ac/50 m² (4000 g ac/ha).⁴⁸ Accordingly, this use also exceeds the upper rate identified for an acceptable risk to birds (850 g ac/ha).⁴⁹
64. 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 find that:
- 64.1 single application rates that exceed 850 g ac/ha pose an unacceptable risk to birds;
- 64.2 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
- 64.3 the home garden/urban use spray product class with usage rates > 850 g ac/ha poses an unacceptable risk to birds.
65. For these reasons, on the material currently before the APVMA, the APVMA is not satisfied that the certain uses in 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.

Labelling criteria

66. In relation to determining whether the labels for the products listed in **Annexure A** satisfy the labelling criteria, the APVMA has had regard to and above reasons on human health and environmental assessments; and relevant advice from the Principal Toxicologist set out in the *Reconsideration of chlorpyrifos: Toxicology update (2019)* and the *Reconsideration of chlorpyrifos: Residential exposure and public space use exposure assessment and risk characterisation update (2019)*, and the expert advice from an external scientific reviewer set out in the *Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1—Home garden, domestic and certain non-agricultural uses (2019)*.
67. In considering the instructions on the labels in **Annexure A** against the labelling criteria set out in subsection 5D(1) of the Code, the APVMA considered the following information:

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.

- 67.1 For the purposes of paragraph 5D(1)(a) of the Code regarding *the circumstances in which the product should be used*, it is determined that,
- 67.2 The labels for the products listed in **Annexure A** have certain uses or circumstances in domestic or residential areas, container plants, public spaces to which children have access, potted ornamentals and other potted plants, duboisia (in domestic and public space uses), macrocarpa hedges (in domestic and public space uses), uses on turf and/or lawns to which children have access and mosquito adult/larvae control in vegetation, that are concluded in the *Exposure assessment and risk characterisation report (2019)* to pose unacceptable risks to humans, and therefore to be discontinued.
- 67.3 Labels for the products listed in **Annexure A** have certain uses or circumstances in domestic areas, public places and turf, that have use rates above 850 g ac/ha, that are concluded in the Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019) to pose unacceptable risks to animals, especially birds, and therefore not supported.
- 67.4 For the purposes of paragraph 5D(1)(b) of the Code regarding *how the product should be used*, it is determined that labels for the products listed in **Annexure A** contain certain uses in domestic, public places and turf above 850 g ac/ha that are concluded in the Reconsideration of chlorpyrifos: Supplementary environment assessment report Part 1 – Home garden, domestic and certain non-agricultural uses (2019) to pose unacceptable risks to animals, especially birds, and therefore not supported.
- 67.4 For the purposes of paragraph 5D(1)(f) of the Code regarding *the re-entry period after the use of the product*, the labels for the products listed in **Annexure A** do not have adequate instructions for re-entry after the products are used in domestic or residential areas, container plants, public spaces to which children have access, potted ornamentals and other potted plants, duboisia (in domestic and public space uses), macrocarpa hedges (in domestic and public space uses), uses on turf and/or lawns to which children have access and mosquito adult/larvae control in vegetation, and therefore pose uncontrolled risks to humans, mainly children, on re-entry period into treated areas after the use of the product.

Conclusion on the labelling criteria

68. For these reasons, on the material currently before the APVMA, the APVMA find that the labels for the products listed in Annexure A do not meet the labelling criteria set out in section 5D of the Code. Accordingly, in the APVMA's view, the conditions for the suspension or cancellation of the approval of the labels under subsection 41(2) of the Code are satisfied.

Issue 2 — Suspension of the labels (s41)

69. As the APVMA is not satisfied, on the material currently before the APVMA, that the labels meet the labelling criteria set out in section 5D of the Code, the conditions for the suspension or cancellation of the approval of the labels under subsection 41(2) of the Code are satisfied.
70. In the circumstances, the APVMA exercises its discretion to suspend the approval of the labels for the products listed in Annexure A under subsection 41(2) of the Code.
71. Section 43 of the Code requires the suspension of a registration or an approval to be for a stated period.
72. The APVMA is currently reconsidering the registration of the products, and the approval of labels, under Division 4 of Part 2 of the Code. Noting the ongoing nature of that reconsideration process, the APVMA considers it reasonable that the period of the suspension of the products and labels under section 41 be for a period sufficient for that reconsideration process to conclude. Therefore, as required by section 43
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of the Code, the APVMA decides that the suspension of approval of the labels for the products listed in Annexure A under section 41 of the Code be for a period of 12 months.

ANNEXURE A — CHLORPYRIFOS PRODUCTS WITH CERTAIN USES WHOSE LABEL APPROVALS WERE PROPOSED FOR SUSPENSION ON 24 JUNE 2019

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
Container plants, macrocarpa hedges and agricultural uses			
51211	Lorsban 750 WG Insecticide	Dow Agrosiences Australia Limited	51211/0306 51211/0501 51211/0401
51513	Cyren 500 WP Insecticide	Cheminova Australia Pty Limited	51513/0406 51513/1101
52235	Farmoz Cyren 500 WP Insecticide	Adama Australia Pty Limited	52235/0609 52235/0405 52235/0301
61071	Strike-Out 500 WP Insecticide	Adama Australia Pty Limited	61071/63186 61071/0710 61071/0609 61071/0906
70410	Pyrigran Insecticide	Sulphur Mills Australia Pty Limited	70410/115800 70410/63402
Domestic, public places, commercial and industrial areas			
47760	Master 250 CS Insecticide	Adama Australia Pty Limited	47760/0801
Domestic, commercial, industrial areas and agricultural uses			
49869	4farmers Chlorpyrifos 500 Insecticide	4 Farmers Australia Pty Ltd	49869/56833 49869/0402
Domestic, commercial, industrial areas, turf and agricultural uses			
64319	Farmalinx Chlorpos 500 EC Insecticide	Farmalinx Pty Ltd	64319/59285 64319/0809
69776	Accensi Chlorpyrifos 500 Insecticide	Accensi Pty Ltd	69776/61713
81735	ACP Chlorpyrifos 500 Insecticide	Australis Crop Protection Pty Ltd	81735/103921
86189	Sinon Chlorpyrifos 500 Insecticide	Sinon Australia Pty Limited	86189/114945
Domestic, commercial, industrial areas, potted ornamentals, duboisia, turf and agricultural uses			
42284	David Grays Chlorpyrifos 500	David Gray & Co. Pty limited	42284/0901
53428	Generifos 500EC Insecticide	Grow Choice Pty Limited	53428/59489 53428/0202
54957	WSD Chlorpyrifos 500 EC Insecticide	WSD Agribusiness Pty Ltd	54957/0502

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
55208	Halley Chlorpyrifos 500 Insecticide	Halley International Enterprise (Australia) Pty Ltd	55208/0203 55208/0702 55208/0202
55213	Kenso Agcare Kensban 500 Insecticide	Kenso Corporation (M) SDN. BHD.	55213/0310 55213/0302
55897	Conquest Chlorpyrifos 500 Insecticide	Conquest Crop Protection Pty Ltd	55897/0408 55897/0702
63086	Chemicide 500 Insecticide	Hextar Chemicals Pty Ltd	63086/44672
63145	AW Cuft 500 Insecticide and Termiticide	Agri West Pty Limited	63145/58996 63145/0908
Domestic, commercial, public and industrial areas, hides/skins, potted ornamentals, duboisia, mosquitoes, turf and agricultural uses			
80093	Oztec Chlorpyrifos 500EC Insecticide	Oztec Rural Pty Ltd	80093/100196
Domestic, commercial, public and industrial areas, hides/skins, mosquitoes, turf and agricultural uses			
32902	Nufarm Chlorpyrifos 500 EC Insecticide	Nufarm Australia Limited	32902/0809 32902/1208 32902/1207 32902/0305 32902/0104 32902/0903 32902/0303 32902/0902 32902/0801 (does not include hides/skins, mosquitoes only)
60611	Huilong Chlorpyrifos 500 EC Insecticide	Huilong Agrochemicals Australia Pty Ltd	60611/107504 60611/53005 60611/0806
67170	Novaguard Chlorpyrifos 500 Insecticide	Novaguard Pty Ltd	67170/55388
67451	Sabakem Chlorpyrifos 500EC Insecticide	Sabakem Pty Ltd	67451/113873 67451/105206 67451/56062
67887	Spalding Chlorpyrifos 500 Insecticide	Spalding Holdings Pty Ltd	67887/57029
67984	Ezycrop Chlorpyrifos 500 Insecticide	Ezycrop Pty Ltd	67984/57224
68279	Agro-Essence Chlorpyrifos 500 Insecticide	Agro-Alliance (Australia) Pty Ltd	68279/105168 68279/57925

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
68467	Chlorban 500 EC Insecticide	UPL Australia Limited	68467/101329 68467/101482 68467/61695 68467/58407
69048	Smart Chlorpyrifos 500 Insecticide	Crop Smart Pty Ltd	69048/59718
69990	Agvantage Chlorpyrifos 500 EC Insecticide	Landmark Operations Limited	69990/62243
70062	Macphersons Chlorpyrifos 500 Insecticide	Eurochem Pty Ltd	70062/62409
81786	Chlorphos 500 EC Insecticide	Ruralco Holdings Limited	81786/112047 81786/104053
83310	Sinon Chlorpyrifos 500 EC Insecticide	Sinon Australia Pty Limited	83310/107951
83386	Sharda Chlorpyrifos 500 Insecticide	Sharda Cropchem Espana S.L	83386/108160
83426	Echem Chlorpyrifos 500 Insecticide	Echem (Aust) Pty Limited	83426/108241
84836	Submarino Chlorpyrifos 500 Insecticide	Submarino Pty Ltd	84836/111529
85005	Raystar Chlorpyrifos 500 EC Insecticide	Raystar Cropprotection Pty Ltd	85005/112016
85326	AgProtect Chlorpyrifos 500 EC Insecticide	Agprotect Australasia Pty Ltd	85326/112937
85424	Profeng Chlorpyrifos 500 EC Insecticide	Profeng Australia Pty Ltd	85424/113255
86544	Foison Chlorpyrifos 500 EC Insecticide	Foison Scitech Co. Limited	86544/116014
86612	Arysta LifeScience Chlorpyrifos 500 EC Insecticide	Arysta LifeScience Australia Pty Ltd	86612/116202
Domestic, commercial, public and industrial areas, hides/skins, mosquitoes, termites and agricultural uses			
51190	Imtrade Chlorpyrifos 500 Insecticide	Imtrade Australia Pty Ltd	51190/106298 51190/0809 51190/0502
60188	Genfarm Chlorpyrifos 500 Insecticide	Landmark Operations Limited	60188/52767 60188/0209 60188/1106 60188/0905
65556	Rainbow Chlorpyrifos 500 Insecticide	Shandong Rainbow International Co Ltd	65556/51274
66354	Ozcrop Chlorpyrifos 500 EC Insecticide	Ozcrop Pty. Ltd.	66354/53439
66467	Mission Chlorpyrifos 500 EC Insecticide	Mission Bell Holdings Pty Ltd	66467/53685

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
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Domestic, commercial, public and industrial areas, potted ornamentals, duboisia, hides/skins, mosquitoes, turf, termites and agricultural uses

45486	Strike-Out 500 EC Insecticide	Adama Australia Pty Limited	45486/63149 45486/55444 45486/0609 45486/1008 45486/0107 45486/0903 45486/0602 45486/0701
51875	Pidgeon's Pest Controller 500 Termiticide and Insecticide	Superway Garden Ag & Pest Products Pty Ltd	51875/1206 51875/0406 51875/0402 51875/1100
55755	Surefire Fortune 500 Multi-Purpose Insecticide and Termiticide	PCT Holdings Pty Ltd	55755/108773 55755/0502
65160	Apparent Dingo 500 Insecticide	Apparent Pty Ltd	65160/59930 65160/50307
68745	AC Chop 500 Insecticide and Termiticide	Axichem Pty Ltd	68745/59000
69671	Agrocn Chlorpyrifos 500 EC Insecticide and Termiticide	Shanghai Agrochina Chemical Co Ltd	69671/61400
83508	Agsure Chlorpyrifos 500 Insecticide	Elders Rural Services Australia Limited	83508/108520

Domestic, commercial, public and industrial areas, potted ornamentals, hides/skins, mosquitoes, turf, termites and agricultural uses

52596	Macro Protect Chlorpyrifos 500 Insecticide and Termiticide	Landmark Operations Limited	52596/109155 52596/54145 52596/0203 52596/0102
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Domestic, public, commercial and industrial areas, hides/skins, mosquitoes and termites

39885	Nufarm Chlorpyrifos PCO Insecticide	Nufarm Australia Limited	39885/0801
42039	David Grays PCO Chlorpyrifos 500	David Gray & Co. Pty limited	42039/0501
48625	Cyren PC Insecticide	FMC Australasia Pty Ltd	48625/1201
50452	Titan Chlorpyrifos PC 450 Insecticide	Titan Ag Pty Ltd	50452/0407 50452/0302 50452/0701

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
50956	Creofos Pre-Construction - Post-Construction Termiticide & Insecticide	Creepy Crawly Pest Control Pty Ltd	50956/0601
53013	Optem Duo Termiticide and Insecticide	PCT Holdings Pty Ltd	53013/0302
53192	Country Micro-Lo Pre-Construction/Post-Construction Termiticide and Insecticide	Garrards Pty Ltd	53192/1009 53192/0103 53192/0301
68574	Accensi Micro-Lo Pre-Construction/Post-Construction Termiticide and Insecticide	Accensi Pty Ltd	68574/109102 68574/58615
68575	Accensi Pre-Construction/Post-Construction Termiticide and Insecticide	Accensi Pty Ltd	68575/58616
68729	Contraforce Termiticide & Insecticide	Sherwood Chemicals Australasia Pty Ltd	68729/58966
Domestic, public, commercial and industrial areas, potted ornamentals, turf, hides/skins, mosquitoes and termites			
48770	Farmoz Strike-Out PC Termiticide And Insecticide	Adama Australia Pty Limited	48770/0609 48770/1205 48770/0201

ANNEXURE B — ACCEPTABLE PROFESSIONAL PUBLIC SPACE USES OF CHLORPYRIFOS

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)	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)
Container plants					
Domestic areas					
Domestic uses					
Duboisia (in domestic and public space uses)	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)
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)	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)
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					
Professional use products	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
Mosquito adult/larvae control in water bodies					

Crop/use	Application method	Application rate	Work rate	MOE† [⊗]	Comments
					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 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)
	Backpack	15 g a.c./ha	1 ha/d	92	Required personal protective equipment: Chemical resistant gloves, boots, socks and a double layer of chemical resistant clothing

* 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 US EPA OPREC

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

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:

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

Where:

AR (Application rate); **B** (oral bioavailability): The oral bioavailability data for the active constituent chlorpyrifos is a factor of 0.77 (i.e., 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 (i.e., 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 cm² 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 cm²/h
- one to two-year olds = 49,000 cm²/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.

ANNEXURE E — CHLORPYRIFOS PRODUCT LABELS SUSPENDED BY THIS DECISION

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
Container plants, macrocarpa hedges and agricultural uses			
51513	Cyren 500 WP Insecticide	Cheminova Australia Pty Limited	51513/0406 51513/1101
Domestic, commercial, industrial areas, potted ornamentals, duboisia, turf and agricultural uses			
54957	WSD Chlorpyrifos 500 EC Insecticide	WSD Agribusiness Pty Ltd	54957/0502
55208	Halley Chlorpyrifos 500 Insecticide	Halley International Enterprise (Australia) Pty Ltd	55208/0203 55208/0702 55208/0202
Domestic, commercial, public and industrial areas, hides/skins, potted ornamentals, duboisia, mosquitoes, turf and agricultural uses			
80093	Oztec Chlorpyrifos 500EC Insecticide	Oztec Rural Pty Ltd	80093/100196
Domestic, commercial, public and industrial areas, hides/skins, mosquitoes, turf and agricultural uses			
67170	Novaguard Chlorpyrifos 500 Insecticide	Novaguard Pty Ltd	67170/55388
68279	Agro-Essence Chlorpyrifos 500 Insecticide	Agro-Alliance (Australia) Pty Ltd	68279/105168 68279/57925
69990	Agvantage Chlorpyrifos 500 EC Insecticide	Landmark Operations Limited	69990/62243
70062	Macphersons Chlorpyrifos 500 Insecticide	Eurochem Pty Ltd	70062/62409
84836	Submarino Chlorpyrifos 500 Insecticide	Submarino Pty Ltd	84836/111529
85005	Raystar Chlorpyrifos 500 EC Insecticide	Raystar Cropprotection Pty Ltd	85005/112016
85424	Profeng Chlorpyrifos 500 EC Insecticide	Profeng Australia Pty Ltd	85424/113255
86544	Foison Chlorpyrifos 500 EC Insecticide	Foison Scitech Co. Limited	86544/116014
Domestic, commercial, public and industrial areas, potted ornamentals, duboisia, hides/skins, mosquitoes, turf, termites and agricultural uses			
83508	Agsure Chlorpyrifos 500 Insecticide	Elders Rural Services Australia Limited	83508/108520
Domestic, commercial, public and industrial areas, potted ornamentals, hides/skins, mosquitoes, turf, termites and agricultural uses			

Product number (1)	Product name (2)	Holder (3)	Label approval number (4)
52596	Macro Protect Chlorpyrifos 500 Insecticide and Termiticide	Landmark Operations Limited	52596/109155 52596/54145 52596/0203 52596/0102
Domestic, public, commercial and industrial areas, hides/skins, mosquitoes and termites			
42039	David Grays PCO Chlorpyrifos 500	David Gray & Co. Pty limited	42039/0501
48625	Cyren PC Insecticide	FMC Australasia Pty Ltd	48625/1201
50956	Creofos Pre-Construction - Post- Construction Termiticide & Insecticide	Creepy Crawly Pest Control Pty Ltd	50956/0601
53013	Optem Duo Termiticide and Insecticide	PCT Holdings Pty Ltd	53013/0302
68729	Contraforce Termiticide & Insecticide	Sherwood Chemicals Australasia Pty Ltd	68729/58966