Australian Government
Australian Pesticides and Veterinary Medicines Authority

Fipronil Review

Phase 2
Environmental Assessment Report:

Fipronil

Tier 1 Risk Assessment

prepared by

Department of the Environment, Water, Heritage and the Arts
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1. Predicted environmental concentrations

Use of products from groups 8 (fruit fly baits) and 9 (termiticide dust) are anticipated to result in a very low environmental exposure. These products are not assessed further as their continued use is deemed acceptable based on this very limited exposure.

1.1. Birds, mammals and reptiles

1.1.1. Group 1 and 2 products

The tier 1 predicted environmental concentrations are based on methods described in EPHC, (2009). For spray applications, the PEC_{food} is used for assessing exposure to birds, mammals and reptiles.

DEWHA estimates pesticide concentrations in animal food items with the focus on quantifying possible dietary ingestion of residues on vegetative matter and insects. Residue estimates are based on the updated Kenaga nomogram (Pfleeger et al. 1996) that relates food item residues to pesticide application rate. Residues are then compared with dietary toxicity data or are converted to an oral dose for use in the risk characterisation.

Table V4.1: Residues (mg ac/kg freshweight) for different birds, mammals and reptile dietary components based on different application rates (g ac/ha) in the treated area

	Residues (mg ac/kg fresh weight) based on the following rates (g ac/ha)						
Dietary component	1.25	25	40	50	75	100	800
Short grass	0.3	5.4	8.6	10.7	16.1	21.4	171.4
Leaves; small insects	0.2	3.0	4.8	6.0	9.0	12.1	96.4
Grain/long grass	0.1	2.5	3.9	4.9	7.4	9.8	78.4
Pods with seeds; large insects	0.02	0.33	0.54	0.67	1.0	1.34	10.7
PEC_{food} – Bird diet A	0.13	2.62	4.19	5.24	7.86	10.48	83.81
PEC_{food} – Bird diet B	0.05	0.97	1.55	1.94	2.91	3.88	31.02
PEC_{food} – Mammals / Reptiles	0.2	3.0	4.8	6.0	9.0	12.1	96.4

The ‘Bird diet A’ is representative of quail and assumes the diet is based on 30% small insects and 70% grain/long grass.

The ‘Bird diet B’ is representative of mallard duck, and assumes the diet is 30% grain/long grass and 70% large insects.

The mammal diet assumes 100% small insects in line with an earlier DEWHA assessment for fipronil.

The reptile diet assumes 100% small insects.

DEWHA does not have standard diets for mammals and reptiles. However, for this assessment the above are used as surrogates.

1.1.2. Group 3 and 4 products

The three products in these two groups have a single application rate of 1.25 g ac/ha. Residues and associated PEC values for this application rate are calculated above in Section V4.1.1.1.

1.1.3. Group 5 products

EPHC (2009) describes DEWHA's approach to calculating exposure to birds from seed treatments:

For treated seed applications, the amount of pesticide per unit area is estimated. In this instance, direct consumption of granules, baits or treated seed by birds or mammals forms the basis of the PEC_{food}. The label rate of application for the active constituent (ac) is the basis for the exposure calculation.

Exposed chemical per square metre can be calculated in several ways depending on whether the material is applied in rows or broadcast over the entire application site.

- Broadcast: This is a direct conversion. That is, 1 kg ac/ha = 100 mg ac/m^2.

- Row / band /in-furrow: Information on the actual area within a hectare should be included. For example, if this type of application only results in half the hectare being treated, the application rate of 1 kg ac/ha results in an average 50 mg/m^2. This further assumes there is no incorporation within the rows. Australia tends to assume no incorporation into soil unless the method of application suggests otherwise. In contrast, the US EPA makes the following assumptions:

    - in-furrow applications assume 1% of granules, bait, or seed are unincorporated

    - banded treatments assume 15% of granules, bait, seeds are unincorporated

    - broadcast treatment without incorporation assumes 100% of granules, bait, seeds are unincorporated.

The two group 5 products are registered for seed treatment use with rice, canola, sorghum and sunflowers. Calculations previously used by DEWHA in assessing seed treatment risks to birds for exposure are provided as follows:

Table V4.2: Group 5 summary of uses and maximum application rates

	Rice	Sorghum	Sunflower	Canola
Application type	Broadacre	Row	Row	Row
Mass of 1 seed	26 mg	33 mg	83 mg	2.5–4 mg
Number of seeds per kilogram	38 500	30 000	12 050	250 000–400 000
Application rate of fipronil to seed	0.1 g ac/kg	0.75 g ac/kg	0.75 g ac/kg	2 g ac/kg
Amount of fipronil per seed*	2.6 µg	25 µg	62 µg	5–8 µg
Number of seeds per unit area	460/m^2	6/m row	6/m row	18–30/m row
Amount of fipronil per unit area	120 µg/m^2	150 µg/m row	370 µg/m row	90–240 µg/m

*Assumes complete take up of active by seed.

These exposure calculations assume no soil incorporation.

1.1.4. *Group 6 products*

A similar approach to avian exposure is used as described for seed treatment (Group 5 products above). In the case of granular application to turf, incorporation will occur following application. This incorporation is by irrigation (6 mm). There are no data as to how effective such a method is in reducing the number of granules on the soil surface. For this assessment, several levels of incorporation will be used to illustrate the impact on avian risk, subject to how much chemical remains on the surface. Three levels of incorporation (50%, 75% and 95%) will be modelled. Based on this, the following exposure calculations can be made:

Table V4.3: Fipronil exposure levels following granular application of turf products

Application rate (g ac/ha)	30	60	75
No incorporation (mg/m^2)	3	6	7.5
50% incorporation (mg/m^2)	1.3	3	3.75
75% incorporation (mg/m^2)	0.75	1.5	1.88
95% incorporation (mg/m^2)	0.15	0.3	0.38

1.1.5. *Group 7 products*

The method for estimating the PEC_{food} based on residues following spray application is described above in Section V4.1.1.1. The spray rate for termiticide treatments is 3 g ac/m^2, which corresponds to 30 000 g ac/ha. Using the Kenaga nomogram, the PEC_{food} for birds, mammals and insects (diets as described in Section V4.1.1.1) are as follows:

Table V4.4: Fipronil PEC_{food} levels following granular application of turf products

Application rate	30000 g ac/ha
PEC_{food} – Bird diet A (30% small insects; 70% grain/long grass)	3140 mg/kg
PEC_{food} – Bird diet B (30% grain/long grass; 70% insects)	1160 mg/kg
PEC_{food} – Mammals and Reptiles (100% small insects)	3620 mg/kg

1.2. Aquatic organisms

1.2.1. Group 1 and 2 products

At the initial screening stage, tier 1 exposure concentrations are based on residues calculated from 10% drift into a 1-ha, 15 cm-deep water body. It is assumed exposure is to the unchanged parent compound, so exposure concentrations at this stage only relate to fipronil and not metabolites. Further, several of the application rates described in Section V4.1.1.1 relate to the treated area, which does not correspond to the full hectare (for example, band treatment in bananas and furrow spraying in sugar cane). However, at this tier 1 stage, the treated area is taken as the rate for exposure to the water body. The standard water body in this case has a water volume of 1.5×10^6 L.

It is possible to estimate the likely water column fipronil levels based on known sediment levels using equilibrium partitioning (EqP). As explained in Di Toro et al.(1991), the sediment concentration (Cs) and free dissolved pore water concentration (Cd) share the following relationship:

Cs/Foc = Koc X Cd, or conversely, Cd = Cs/(Foc X Koc)

DEWHA assumes sediment has a fraction of organic carbon (Foc) of 2%. While there are no measured data for fipronil, there are several results for the main metabolites (sulphide (MB45950), desulfinyl (MB46513) and sulfone (MB46136)) from *Chironomus tentans* sediment studies where sediment and corresponding pore water concentrations were measured. These studies have not been provided to the APVMA, but are reported in the EFSA review. Further, there are studies (see Volume 2) measuring Koc values in a number of soils for each of these compounds. These data were used to test the sensitivity of the above relationship where the geometric mean Koc for each substance was used. It was demonstrated that the formula, when tested to estimate the pore water concentration in sediment based on measured sediment levels, was rarely wrong by a factor of 2 or more. In fact, for the more strongly sorbed compounds (MB45950 and MB46136), the mean difference between measured and estimated values was 1.3 times. For the less strongly sorbed MB46513, the mean difference was 1.8, and at all sediment concentrations, the formula overestimated the pore water concentration.

The opposite was therefore true for predicting sediment concentrations from known pore water levels, and for the less strongly sorbed MB46513, the formula underpredicted sediment concentrations by 1.8 times.

This information is being used in the absence of other data to predict fipronil sediment levels based on overlying water concentrations. Fipronil is less strongly sorbed than MB46513, so it is considered probable that the sediment predicted concentrations may be underestimated.

The following exposure concentrations are calculated:

Table V4.5: Predicted water (µg/L) and sediment (µg/kg) concentrations following 10% drift to a standard water body for the range of rates in Group 1 and 2 products

	Application rate in the treated area (g ac/ha)						
Predicted concentrations	1.25	25	40	50	75	100	800
Water (µg/L) Sediment (µg/kg)	0.83 11	16.7 225	26.7 360	33.3 449	50 674	66.7 899	533 7185

1.2.2. Group 3 and 4 products

The three products in these two groups have a single application rate of 1.25 g ac/ha. Predicted concentrations in water and sediment for this application rate are calculated above in Section V4.1.2.1.

1.2.3. Group 5 products

In the assessments of aquatic exposure through the various seed treatment uses, DEWHA previously only considered such exposure could result from the seed-treatment use in rice. To this end, it was reported that fipronil is added to rice as a seed treatment, applied to pre-germinated rice seed through nozzles as the seed is conveyed into the aeroplane hopper for immediate aerial sowing. Bays are flooded with water prior to sowing, to a depth of 10–15 cm and the application rate is equivalent to around 12.5 g ac/ha as the seed treatment.

A study submitted at the time of the rice seed treatment application in Australia showed that 24 hours after application, 18–23% of initial application rates are found in the water column (Stevens & Helliwell 1996). At the application rate of 12.5 g ac/ha (seed treatment) for this product, the level of fipronil found in the water column immediately following sowing was 2.11 µg/L (or around 17% of the applied rate).

1.2.4. Group 6 products

When turf use was first assessed by DEWHA, it was considered that aquatic systems would not be significantly exposed through this use. However, application rates at that time were lower than currently registered, and there is new information suggesting aquatic organisms may be much more sensitive than initially thought. Consequently, the potential aquatic risk needs to be revisited.

Because turf products are applied in granular form, there will not be a spray drift concern (APVMA 2008). However, the following screening approach is taken for consideration of runoff, for example, from golf fairways or turf farms to nearby natural water bodies. It will be assumed that no runoff occurs during the incorporation stage (6 mm irrigation following application). However, based on three levels of incorporation, given the lack of data on the efficiency of 6 mm to incorporate all granules, a predicted concentration in water will be calculated assuming 10% runoff following a rain event into a standing body of water 1-ha surface and 15 cm deep. The three levels of incorporation considered will be 50%, 75% and 95%. The following water concentrations are calculated along with corresponding sediment concentrations calculated based on the methodology described in Section V4.1.2.1 above:

Table V4.6: Predicted water and sediment concentrations based on different levels of incorporation

Application rate (g ac/ha)		30	60	75
Water concentration (µg/L)	50% incorporation	1.0	4.0	5.0
	75% incorporation	0.5	2.0	2.5
	95% incorporation	0.1	0.4	0.5
Sediment concentration (µg/kg)	50% incorporation	13	54	67
	75% incorporation	7	27	34
	95% incorporation	1	5	7

1.2.5. *Group 7 products*

Fipronil as a termiticide will be applied either by conventional spraying such as hand-sprayer lance delivering a low pressure, high volume spray, or by soil-injection equipment such as trenching and backfill or soil rodding. All of this will be applied directly to the soil and, despite the high application rate, the extent of spray drift may be expected to be very low due to the coarse droplet size and unlikely to be of concern.

However, exposure from runoff needs to be considered. Very high application rates (30 000 g ac/ha in the treated area) could potentially lead to higher mobility, particularly if soil saturation is approached. Runoff from trenching or rodding application is not expected as the substance is fully incorporated.

In the initial assessment, DEWHA considered as a worst case application to a number of existing houses in areas of medium density building and assumed treated areas (houses and surrounding paths) averaged 200 m^2, and blocks averaged 500 m^2. Therefore, for this ‘standard’ block, up to 600 g of fipronil could be applied.

The amount of chemical available in runoff will be a function of the number of treated houses in an area, the time from when each house was treated until the runoff event, and how much chemical in runoff associates with vegetation or soil in untreated areas during runoff. There is no easy way to quantify any of this. Except for pre-construction use in housing estates, it is unlikely that a significant proportion of buildings would be treated with fipronil at the same time in any given area, where this chemical is then mobilised in a runoff event. However, it can be seen that in a localised situation, elevated levels of fipronil may be found in runoff waters if sufficient rainfall occurs shortly after treatment. For example, if based on the 'standard' house described above, rainfall causes 10% of the applied to run into a nearby pond of 1-hectare surface area and 15 cm deep, the water concentration would be in the area of 40 µg/L.

1.3. Terrestrial invertebrates

1.3.1. Group 1 and 2 products

Exposure to bees is determined for spray applications based on the maximum application rate. This rate is converted to a rate of chemical (ac) per square centimetre ($PEC_{surface}$) on the assumption that a honeybee is approximately 1 cm^2 in surface area (Davis & Williams 1990).

Exposure to other arthropods (for example, predators, parasites and ground dwelling organisms) is determined for spray applications based on the maximum application rate in g ac/ha.

The exposure calculations for soil organisms such as earthworms, soil-dwelling arthropods and soil microorganisms are based on the application rate of the chemical. With regard to these situations, the concentration in soil is predicted based on uniform mixing within the top 10 cm using a soil density of 1500 kg/m^3 (PEC_{soil}).

A tier I risk assessment was performed in this case based on the methods outlined in ESCORT 2 (Candolfi et al. 2000). Both in-field and off-field risk are considered. However, the methodology for off-field risk was modified from ESCORT 2. This document refers to ground drift estimates based on data not used by the APVMA. Consequently, spray drift was estimated using AGDRIFT, with a downwind terrestrial deposition width of 3 m, with drift estimated at 0 m downwind from the edge of the field. For off-field exposure, ESCORT 2 suggests using a vegetation distribution factor to account for the likelihood that off-field areas are vegetated compared with the bare ground characteristics used in generating drift data (thereby trapping drift and lowering exposure). They also recommend a correction factor be applied to the ecotoxicity end point to account for expected higher diversity of species found off-field. A factor of 10 is suggested for both these corrections. As these cancel each other out in the formula, they were not used for this assessment.

At the edge of the field, AGDRIFT estimates a drift fraction of 0.5181 of the application rate (high boom; 90th percentile data; very fine to fine droplets (= fine spray)) or 0.1627 of the application rate (high boom; 90th percentile data; fine to medium/coarse droplets (= medium spray)).

The following table provides these PEC calculations for a range of application rates.

Table V4.7:Terrestrial PEC calculations based on different application rates of fipronil

Application rate (g/ha)	1.25	25	40	50	75	100	800
$PEC_{surface}$ (µg/cm^2)	0.0125	0.25	0.40	0.5	0.75	1	8
PEC_{soil} (mg/kg)	0.0008	0.017	0.027	0.033	0.05	0.067	0.53
In-field PEC (g ac/ha)	1.25	25	40	50	75	100	800
Off-field PEC (g ac/ha)[1]	0.65	13	21	26	39	52	414
Off-field PEC (g ac/ha)[2]	0.20	4.1	6.5	8.1	12	16	130

[1] Fine droplet size; [2] Medium droplet size (AGDRIFT Model).

1.3.2. Group 3 and 4 products

The three products in these two groups have a single application rate of 1.25 g ac/ha. Terrestrial PEC values for this application rate are calculated above in Section V4.1.3.1.

1.3.3. Group 5 products

DEWHA's initial assessment of exposure to bees through seed treatments in rice, canola, sorghum and sunflowers was as follows:

> When used as a seed treatment for the above crops, the method of application and absence of other flowering species in rice bays and fields at the time of application suggests a low environmental exposure to bees.

Terrestrial non-target arthropods will not be exposed through spray when fipronil is used as a seed treatment. However, where desorption from treated seeds occurs, there may be some exposure through the soil. In the case of rice, DEWHA had previously concluded a low risk given the anaerobic nature of rice bay sediments suggesting soil invertebrates would not be present, and there would be limited microbial activity. The following theoretical (worst case) exposure calculations are provided for maximum soil concentrations based on the equivalent per hectare rate for canola, sorghum and sunflowers, assuming all fipronil applied with the treated seed is distributed through the top 10 cm soil using a soil density of 1500 kg/m^3 (PECsoil).

Table V4.8: PEC_{soil} based on different application rates of fipronil

Crop / application rate (kg/ha)	Canola (10 g ac/ha)	Sorghum (9 g ac/ha)	Sunflowers (4 g ac/ha)
PEC_{soil} (mg/kg)	0.007	0.006	0.003

1.3.4. Group 6 products

Terrestrial non-target arthropods will not be exposed through spray when fipronil is used as a granular turf treatment. However, following watering in of granules, there may be some exposure through the soil. The following theoretical (worst case) exposure calculations are provided for soil concentrations assuming three levels of incorporation (50%, 75% and 95%) with residues distributed through the top 10 cm soil using a soil density of 1500 kg/m^3 (PECsoil).

Table V4.9: PEC_{soil} based on different application rates of fipronil

Application rate (g ac/ha)		30	60	75
PEC_{soil} (mg/kg)	50% incorporation	0.01	0.02	0.025
	75% incorporation	0.015	0.03	0.037
	95% incorporation	0.019	0.038	0.047

1.3.5. *Group 7 products*

The spray rate of 30 000 g ac/ha will result in predicted soil concentrations of 20 mg ac/kg assuming distribution through the top 10 cm soil with a density of 1500 kg/m^3.

In addition to spray applications, in-soil treatments can result in high levels of fipronil with application rates of 60 g ac/m^3 soil (equating to soil residues of 40 mg/kg soil assuming a soil density of 1500 kg/m^3).

2. Risk quotients – tier 1

2.1. Birds, mammals and reptiles

The following is a summary of the ecotoxicity end points used in the risk assessment:

Table V4.10: Summary of bird, mammal and reptile ecotoxicity end points

	Acute LD50	Dietary LC50	Chronic NOEC
Birds	11.3 mg/kg bw	48 mg/kg diet	10 mg/kg diet
Mammals	97 mg/kg bw	–	–
Reptiles	30 mg/kg bw	–	–

In earlier assessments of fipronil, it was observed that reproduction studies carried out on Bobwhite quail suggest adult birds were generally in the weight range of 220–224 g, and could consume around 24 g of seed per day. This equates to a food intake rate to body weight ratio of around 0.11. Australia does not have defined indicator species for birds, and as a worst case risk assessment, this ratio will be used to define intake in terms of mg/kg bw/day.

Previously for fipronil DEWHA has used as a model mammal, the Brown antechinus. An adult male weighs approximately 35 grams, and will consume in the order of 5 grams of food per day (food intake rate/body weight = 0.14). The diet was taken to be 100% small insects, and sensitivity was assumed to be the same as the single rat result (LD50 = 97 mg/kg bw).

Previously for fipronil, DEWHA has assumed for lizards a food intake rate/body weight = 0.2. The diet is assumed to be 100% small insects.

2.1.1. Group 1 and 2 products

Acute risk

For a bird with the sensitivity of a bobwhite quail (LD50 = 11.3 mg/kg), a direct comparison with the LD50 is made based on the residues in the above diet (concentration) converted to mg/kg (dose) consumed. For example, at 100 g ac/ha in the treated area, it was calculated that 10.48 mg/kg fresh weight would be available to a bird with Diet A. If a bird consuming 0.11 times its body weight in a single feed (total daily food intake) following exposure, this equates to 1.15 mg/kg unit of feed for each kg unit of bird. Therefore, a 1 kg bird would consume 1.15 mg fipronil and with an LD50 of 11.3 mg/kg, the Q-value would be 0.1. Similarly, a 100 g bird would consume 0.115 mg fipronil and the Q-value remains the same at 0.1.

The following Q-values are found for acute oral toxicity:

Table V4.11: Birds, mammals, reptiles – acute risk quotients

	Application rates (g ac/ha)						
Dietary component	1.25	25	40	50	75	100	800
Q – Bird diet A	0.001	0.026	0.04	0.05	0.08	0.10	0.82
Q – Bird diet B	0.0005	0.009	0.015	0.019	0.028	0.038	0.30
Q – Mammals	0.0002	0.004	0.007	0.009	0.013	0.017	0.14
Q – Reptiles	0.001	0.02	0.032	0.04	0.06	0.08	0.64

The results for birds are conservative in that the most sensitive LD50 was used (bobwhite quail), while it is known there are other less sensitive species. Further, it is assumed the whole daily intake occurs from within the treated area following application. The assessment indicates that at application rates exceeding 100 g ac/ha, the acute risk to birds is unacceptable, particularly where they have a higher herbivorous diet.

The results for mammals and reptiles need to be treated with some caution. Toxicity results for each are only available for single species, and the results for the rat are extrapolated to Australian native fauna. Further, the values used for FIR/bw are estimates only with no firm data available to confirm these. Based on the assumptions used, the risk to reptiles appears to approach unacceptable levels at rates higher than 100 g ac/ha, while for mammals, it is unacceptable at the highest modelled rate of 800 g ac/ha, but the Q-value is at the low end of the unacceptable range suggesting this risk could be mitigated.

Dietary risk

The lowest avian LC50 from dietary exposure was 48 mg ac/kg diet found with the bobwhite quail. For the dietary risk assessment, this is compared directly to the dietary residues (PEC_{food}) determined above.

Table V4.12: Birds, mammals, reptiles – dietary risk quotients

	Application rates (g ac/ha)						
Dietary component	1.25	25	40	50	75	100	800
Q – Bird diet A	0.002	0.054	0.087	0.11	0.16	0.22	1.75
Q – Bird diet B	0.001	0.02	0.032	0.04	0.06	0.08	0.65
Q – Mammals	Insufficient data						
Q – Reptiles	Insufficient data						

The dietary risk quotients for birds are very conservative as they assume birds continuously consume their entire diet from the treated area, and residues on food remain at initial levels throughout the exposure period. With these assumptions, the risk quotients to birds with Diet A exceed 0.1 at application rates of 50 g ac/ha and higher, while for those with Diet B, the acceptable risk quotient is exceeded at rates exceeding 100 g ac/ha.

Reproductive risk

The lowest avian longer-term NOEC from reproduction tests was 10 mg ac/kg diet found with the bobwhite quail. For the reproductive risk assessment, this is compared directly to the dietary residues (PEC_{food}) determined above.

Table V4.13: Birds, mammals, reptiles – chronic (reproduction) risk quotients

	Application rates (g ac/ha)						
Dietary component	1.25	25	40	50	75	100	800
Q – Bird diet A	0.013	0.26	0.42	0.52	0.79	1.0	8.4
Q – Bird diet B	0.005	0.10	0.16	0.19	0.29	0.39	3.1
Q – Mammals	Insufficient data						
Q – Reptiles	Insufficient data						

These chronic risk quotients for birds are very conservative as they assume birds continuously consume their entire diet from the treated area, and residues on food remain at initial levels throughout the exposure period. With these assumptions, the risk quotients to birds from both modelled diets exceed 1.0 at application rates above 100 g ac/ha.

2.1.2. Group 3 and 4 products

The three products in these two groups have a single application rate of 1.25 g ac/ha. Associated Q-values for birds, mammals and reptiles for this application rate are calculated above in Section V4.2.1.1. These Q-values show an acceptable risk to birds, mammals and reptiles at this level.

2.1.3. Group 5 products

Acute risk

For seed treatments, risk is considered as a function of the number of LD50's available/m^2, or in the case of sorghum, sunflower and canola, the number of LD50's in a 1-metre row. This therefore makes the number of LD50s available per unit a function of a bird's weight as larger birds will need to consume seeds over a larger area than smaller birds to take in a lethal dose. When assessing avian risk in the initial seed treatment assessments, DEWHA considered an adult quail weighing 220 g with the most sensitive LD50 of 11.3 mg/kg bw. For consistency, this 'bird' will also be used for rice in the screening assessment. Using values from Table V4.2, Section V4.1.1.2 for the number of seeds, their weights, and residues of fipronil/seed, the following were calculated:

Table V4.14: Risk characterisation for birds from Group 5 products

	Rice	Sorghum	Sunflower	Canola
Unit area needed to forage	20.7 m^2	16.6 m	6.7 m	10.4 – 27.6 m
LD50's per m^2 (or 1-metre row in this case)	0.05	0.06	0.15	0.10

EPHC (2009) does not provide further guidance on interpreting risk from such an approach where the risk arises through an area of foraging (as opposed to being exposed through residues of foliage/insects resulting from spray applications). However, current guidance provided in the APVMA MORAG (APVMA 1997) provides methodology related to risk to birds from granules that can be extended to seed treatments. In this case, risk is based on the number of LD50s per metre^2. If it is assumed that rows for sorghum, sunflower and canola are 1 metre apart, then the number of LD50's per m^2 is calculated in the above table based on the bird characteristics described above. Up to 10 LD50s per metre^2 is considered to be an acceptable risk, meaning the risk from all use patterns above is acceptable for this assessment. It can readily be seen that smaller birds with a higher seed diet will be more at risk in that they will have a much higher number of LD50s available within the square metre. However, they also will consume relatively lower amounts of food than larger birds.

In terms of sorghum, sunflowers and canola, however, the above calculations assume there is no soil incorporation. In practice, this is unlikely to be the case and the need for birds to dig up seeds may lower their exposure somewhat. However, no quantitative assessment is possible in this regard due to a lack of data.

In the original assessments for the seed treatments, DEWHA an important mitigating factor was the demonstrated repellency of fipronil to birds. However, this was based on a bird monitoring study undertaken in response to the assessment for fipronil as a seed treatment on rice.

Despite this, there is at present, no standard methodology for a higher-tiered risk assessment for bird risk exposed through treated seed. Mitigation of risk, particularly for sorghum, sunflowers and canola is achieved through sowing seed in specifically prepared seed beds followed by incorporation thereby decreasing their ready availability. Further, birds are likely to take daily food intake from areas other than the treated seeds thereby further decreasing their exposure.

Birds' avoidance of treated seed will reduce exposure. However, no standard guideline for testing avoidance is as yet available. Some new data are considered in Volume 3, but these are not easy to interpret, particularly as to how they may relate to behaviour in the field. The use of an 'avoidance factor' in lowering exposure calculations is no longer considered scientifically sound in the EU (EFSA 2008). However, as stated in this document, there is wide agreement among scientists that food avoidance is an important factor that frequently occurs in the field, as such should be considered when refining risk assessments.

Given this, the original DEWHA conclusions for avian risk through exposure to treated seed should remain, that is, these uses do not pose an unacceptable risk to birds. DEWHA is unaware of any information provided to the APVMA, or in the wider literature, implicating fipronil in bird deaths in the field.

2.1.4. Group 6 products

For granular applications, risk is considered as a function of the number of LD50's available/metre^2, or in the case of sorghum, sunflower and canola, the number of LD50s in a 1-metre row. This therefore makes the number of LD50s available per unit a function of a bird's weight as larger birds will need to consume seeds over a larger area than smaller birds to take in a lethal dose. When assessing avian risk in the initial turf assessment, DEWHA considered the case of a 50 g bird. However, for consistency with seed treatments above, an adult quail weighing 220 g with the most sensitive LD50 of 11.3 mg/kg bw will be used in this assessment. Using values from Table V4.3, Section V4.1.1.4 for the granular exposure levels, the following were calculated:

Table V4.15: Risk characterisation for birds from turf application (Group 6 products)

Application rate (g ac/ha)	30	60	75
Number of LD50s per m^2			
No incorporation (mg/m^2)	1.2	2.4	3.0
50% incorporation (mg/m^2)	0.6	1.2	1.5
75% incorporation (mg/m^2)	0.3	0.6	0.76
95% incorporation (mg/m^2)	0.06	0.12	0.15

Based on APVMA (1997) and using a guide that risk is acceptable where up to 10 LD50s are found per metre^2, the risk to birds from turf applications, even assuming no incorporation, is acceptable.

2.1.5. Group 7 products

Following methodology described in Section V4.2.1.1 above, the acute Q-values for birds are 28 (diet A) and 10.3 (diet B). The acute Q-value for mammals is 4.7 while that for lizards is 21.7. All these acute Q-values are indicative of an unacceptable risk.

The dietary Q-value for birds is 65 (diet A) and 24 (diet B), again both indicative of an unacceptable risk. There are insufficient data to determine a dietary Q-value for mammals and reptiles.

The reproduction Q-values for birds is 314 (diet A) and 116 (diet B), both also indicative of an unacceptable risk.

These risk quotients are calculated on the basis that birds and mammals take all their food from within contaminated food in the treated area, and they consume their daily food allowance in a single dose from this area (acute), or continually over a period of time (dietary and reproduction). Such assumptions are clearly too conservative in the case of termiticide use around buildings and the risks are expected to be very much lower than these screening level Q-values indicate.

At the time of assessing the termiticide use application in Australia, DEWHA concluded with respect to birds that contaminated insects are unlikely to comprise the whole of the diet. Further, few native species of mammals are likely to inhabit these areas on a regular basis, and few, if any reptile species are likely to occur in or around the treated areas. Consequently, an acceptable risk was concluded.

It is difficult to refine the risk assessment to birds, mammals and reptiles in a quantitative manner for these termiticide uses, and the original conclusions made by DEWHA remain valid.

2.2. Aquatic organisms

The following end points are used in the risk assessment:

Table V4.16: Summary of aquatic ecotoxicity end points

Aquatic organisms (parent fipronil)				
Fish – acute	Bluegill sunfish	LC50	85	µg/L
Fish – chronic	Sheepshead minnow[1]	NOEC	2.8	µg/L
Aq. invertebrates acute	Mysid shrimp	LC50	0.14	µg/L
Aq. invertebrates chronic	Mysid shrimp[1]	NOEC	0.0077	µg/L
Algae/aquatic plants	Green algae	EC50	68	µg/L
Sediment organisms	*Chironomus tentans*[1]	10 d LC50	0.90	µg/kg

[1] New data resulting in revised (downwards) ecotoxicity endpoints from those initially applied.

These ecotoxicity end points are compared with the predicted water concentrations for the respective product groups as calculated in Section V4.1.2 are used to obtain the following Q-values.

2.2.1. Group 1 and 2 products

Table V4.17: Aquatic organisms – risk quotients

	Aquatic risk quotients based on the following application rates (g ac/ha)						
	1.25	25	40	50	75	100	800
Acute risk auotients							
Fish – acute	0.009	0.20	0.31	0.39	0.59	0.78	6.3
Aq. invertebrates acute	5.93	120	190	240	360	480	3800
Algae / aquatic plants	0.01	0.25	0.39	0.49	0.74	0.98	7.8
Sediment organisms	12	250	400	500	750	1000	8000
Chronic risk quotients							
Fish – chronic	0.30	6.0	9.5	11.9	17.8	23.8	190
Aq. invertebrates chronic	110	2170	3500	4300	6500	8700	69000
Sediment organisms	Insufficient data						

This screening assessment indicates a risk to aquatic organisms at all application rates with the exception of an acceptable risk to fish and algae/aquatic plants at the lowest 1.25 g ac/ha modelled. A refined risk assessment considering aquatic exposure through both spray drift and runoff is required based on the new aquatic toxicity data available since the original fipronil assessments.

2.2.2. Group 3 and 4 products

The three products in these two groups have a single application rate of 1.25 g ac/ha. Associated aquatic Q values for this application rate are calculated above in Section V4.2.2.1. At this rate, the acute risk to fish and algae/aquatic plants is acceptable and the chronic risk to fish is acceptable. The acute risk to aquatic invertebrates and sediment organisms using this tier 1 approach is deemed unacceptable, as is the chronic risk to aquatic invertebrates. There are insufficient data to further consider the chronic risk to sediment organisms. Risks to aquatic invertebrates and sediment organisms will be the subject of a more refined risk assessment considering exposure through spray drift and runoff.

2.2.3. Group 5 products

In the assessments of aquatic risk through the various seed treatment uses, DEWHA concluded with respect to sorghum, sunflowers and canola that the sorption tendencies of fipronil suggest with this fipronil already bound to seed, it is unlikely to desorb from the seed or surrounding soil in sufficient quantities to migrate to waterbodies. Risk to aquatic organisms was therefore deemed acceptable for this use.

Rice

Water is not released from the bays during the life of the crop, and based on information available at the time, DEWHA observed that fipronil did not appear persistent in paddy rice water. Based on data from Stevens and Helliwell (1996), by day 22, the level of fipronil in the water was below the detection limit of 0.005 ppb. This is several orders of magnitude below the most sensitive environmental effects concentration of LC50 = 0.14 ppb for Mysid shrimp, and gives a Q value of <<1. The next most sensitive environmental effects concentration was EC50 = 36 ppb for *Daphnia*, giving a safety factor of several orders of magnitude. Although water is maintained in the bays for several months prior to release, if it was released after 22 days a hazard to aquatic species is unlikely to exist.

A heavy rain immediately after sowing may result in movement of fipronil into surrounding water bodies. If 100 mm of rain fell on a 1-ha bay the day after sowing, the overflow would be 1 ML, which would contain fipronil at a concentration of 3.13 µg/L (assuming a worst case of 50% desorption). This would be further diluted in any receiving water, and after heavy rain, fipronil is likely to only be present in sub ppb levels. Therefore, this was concluded as unlikely to present a risk to aquatic species.

This conclusion is no longer supported in light of information available since the original rice application was assessed. Using the screening level overflow concentration of 3.13 µg/L (42 µg/kg sediment based on equilibrium partitioning methodology described above), the following aquatic Q-values are calculated:

Table V4.18: Aquatic organisms – risk quotients through screening level assessment of rice seed treatment

	Q-value
Fish – acute	0.04
Aq. invertebrates acute	22.4
Algae / aquatic plants	0.05
Sediment organisms	47
Fish – chronic	1.1
Aq. invertebrates chronic	406
Sediment – chronic	Insufficient data

A refined assessment using new data on both toxicity of fipronil and its main metabolites, along with data on the formation and decline of the main (toxic) metabolites will be performed for this use pattern.

2.2.4. Group 6 products

Based on the screening level water concentrations estimated above in Section V4.1.2.4 the following aquatic Q values are found:

Table V4.19: Aquatic organisms – risk quotients through screening level assessment of granular application to turf – 50% incorporation

Application rate (g ac/ha)	30	60	75
Fish – acute	0.01	0.05	0.06
Aq. invertebrates acute	7	29	36
Algae / aquatic plants	0.01	0.06	0.07
Sediment organisms	14	60	74
Fish – chronic	0.36	1.4	1.8
Aq. invertebrates chronic	130	520	650
Sediment – chronic	Insufficient data		

Table V4.20: Aquatic organisms – risk quotients through screening level assessment of granular application to turf – 75% incorporation

Application rate (g ac/ha)	30	60	75
Fish – acute	0.01	0.02	0.03
Aq. invertebrates acute	3.6	14	18
Algae / aquatic plants	0.01	0.03	0.04
Sediment organisms	7.8	30	38
Fish – chronic	0.18	0.71	0.89
Aq. invertebrates chronic	65	260	325
Sediment – chronic	Insufficient data		

Table V4.21: Aquatic organisms – risk quotients through screening level assessment of granular application to turf – 95% incorporation

Application rate (g ac/ha)	30	60	75
Fish – acute	0.001	0.005	0.01
Aq. invertebrates acute	0.71	2.9	3.6
Algae / aquatic plants	0.001	0.01	0.01
Sediment organisms	1.1	5.6	7.8
Fish – chronic	0.04	0.14	0.18
Aq. invertebrates chronic	13	52	65
Sediment – chronic	Insufficient data		

With an assumption of 75% or more incorporation, the acute and chronic risk to fish and the risk to algae/aquatic plants are acceptable. However, even with 95% incorporation assumed, the acute and chronic risk to aquatic invertebrates, and the acute risk to sediment organisms, is unacceptable. These issues will be addressed further in a refined risk assessment.

2.2.5. Group 7 products

Estimated aquatic exposure from runoff as previously described by DEWHA (40 µg/L, see Section V4.1.2.5) is well in excess of both acute and chronic toxicity values for aquatic invertebrates, so a risk is concluded.

The issue of aquatic exposure through termiticide use patterns is not something that can easily be considered in a screening assessment, and will therefore be considered in a refined risk assessment.

2.3. Terrestrial invertebrates

The following end points will be used in the risk assessment:

Table V4.22: Summary of terrestrial invertebrate end points for risk characterisation

Bees (oral toxicity) Bees (contact)	New data are available showing the highly sensitive nature of bees to fipronil. A higher tier risk assess for bees is required based on these data.			
Non-target terrestrial arthropods (exposure through spray)		LR50	0.106	g ac/ha
Non-target terrestrial arthropods (exposure through soil) – collembola		NOEC	0.04	mg/kg dw
Earthworms (based on soil concentration)		NOEC	1000	mg/kg dw
Soil microorganisms	(<25% effects at day 28)	NOEC	0.667	mg/kg dw
Non-target terrestrial plants (end point based on plant height data)		ER25	–	g ac/ha

These ecotoxicity end points are compared with the predicted water concentrations for the respective product groups as calculated in Section V4.1.3 are used to obtain the following Q-values.

2.3.1. Group 1 and 2 products

Regulatory studies provided showed both contact and oral routes of exposure to honey bees resulted in 48-hour LD50s 0.00593 µg ac/bee and 0.00417 µg ac/bee respectively. Based on contact toxicity, the following Q-values are obtained for the different spray application rates of fipronil (200 g/L and 800 g/kg products). These values are used for the screening assessment, but as noted above, a higher tier risk assessment will be required for bees.

Table V4.23: Terrestrial invertebrate Q-values based on different application rates of fipronil

Application rate (g/ha)	1.25	25	40	50	75	100	800
Bees	2.1	42	67	84	125	170	1350
Earthworms	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Soil microorganisms	<0.001	0.025	0.04	0.049	0.07	0.10	0.79
Non-target terrestrial arthropods							
In-Field Q_{Soil}	0.02	0.42	0.68	0.83	1.25	1.7	13
In-Field Q_{Spray}	12	236	380	470	710	940	7550
Off-Field Q-Values[1]	6	120	200	245	370	490	3900
Off-Field Q-Values[2]	2	38	60	77	110	150	1230

[1] Fine droplet size.

[2] Medium droplet size (AGDRIFT Model).

Q-values show an exceedence of levels of concern (Q-values >1, EPHC 2009) for all application rates to bees. Further, there are new data showing even higher toxicity of fipronil to bees than that expressed from the regulatory data previously available. A higher tier risk assessment for bees is required.

The risk to earthworms in the treated area at all application rates of fipronil is deemed acceptable.

Australia has no established levels of concern for soil microorganisms. In the case of non-target soil microorganism exposure, an unacceptable risk is presumed in the event that nitrogen turnover or carbon mineralisation is affected by more than 25% (EPHC 2009). In this tier 1 assessment, the Q-values are below 1 for all application rates, meaning that at these rates, impacts on nitrogen turnover or carbon mineralisation were not affected by more than 25% at the maximum available test rate of 0.667 mg/kg soil. Therefore, the risk to soil microorganisms in the treated area at all application rates of fipronil is deemed acceptable.

Australia has no set level of concern for characterising risk to terrestrial arthropods based on these Q-values. However, ESCORT 2 does provide methodology in this regard, where risk quotients <2 are considered indicative of low risk. The tier 1 risk assessment is based on risk quotients to two species, *A. rhopalosiphi* and *T. pyri* which conform to the available data for this assessment for exposure through spray.

Applying an acceptable Q-value of <2, the above table indicates there is a low risk to in-field soil-dwelling arthropods at application rates up to 100 g ac/ha, however, fipronil may present a risk to these organisms at rates higher than this. For terrestrial arthropods potentially exposed through spray contact, the in-field and off-field risk (at the edge of the field) is unacceptable at all application rates. A higher tier assessment is required to further address this.

2.3.2. Group 3 and 4 products

The three products in these two groups have a single application rate of 1.25 g ac/ha. Associated terrestrial invertebrate Q-values for this application rate are calculated above in Section V4.2.3.1. From this tier 1 approach, the risk to earthworms, soil microorganisms and soil-dwelling invertebrates is considered acceptable. However, the risk to non-target arthropods exposed directly to the spray (bees and other non-target terrestrial arthropods) is deemed unacceptable. A higher tier risk assessment will further consider these organisms.

2.3.3. Group 5 products

DEWHA’s initial assessment of risk to bees through exposure to seed treatments in rice, canola, sorghum and sunflowers concluded a low environmental risk to bees resulting from a lack of exposure.

There are new studies (see Section V3.8.1.1.3, Volume 3) for bees exposed to plants grown from treated seed (sunflowers) in which no adverse effects on mortality, behaviour and colony development were found, which appears to support this conclusion. However, the withdrawal of use of imidacloprid (another systemic insecticide) as a sunflower seed treatment in France following its implication in decline of bee populations and honey production shows this issue needs to be considered very carefully. This issue will be explored further in the refined risk assessment.

While terrestrial non-target arthropods will not be exposed through spray when fipronil is used as a seed treatment, desorption from treated seeds was considered as a source of exposure to soil-dwelling organisms and the PEC_{soil} values are calculated above. Based on these, the following Q-values were calculated:

Table V4.24: Soil-dwelling organism Q-values through fipronil seed treatment uses

Crop / Application rate (kg/ha)	Canola (10 g ac/ha)	Sorghum (9 g ac/ha)	Sunflowers (4 g ac/ha)
Q – earthworms	<<0.001	<<0.001	<<0.001
Q – non target terrestrial arthropods	0.18	0.15	0.10
Q – soil microorganisms	0.01	0.009	0.004

These calculations indicate an acceptable risk to terrestrial non-target organisms including earthworms, non-target terrestrial arthropods and soil microorganisms from fipronil seed-treatment uses in canola, sorghum and sunflowers.

2.3.4. Group 6 products

DEWHAs initial assessment for bees and other non-target terrestrial arthropods, and soil-dwelling invertebrates concluded that while some non-target mortality may be expected (for soil-dwelling invertebrates), the effects will be localised. No risk to bees was concluded based on the granular formulation being used.

The conclusion for bees remains unchanged. However, the higher registered turf rates compared with those initially considered means potential risk to soil-dwelling invertebrates should be reconsidered.

PEC_{soil} values are calculated in Section V4.1.3.4. Based on these, the following Q-values were calculated:

Table V4.25: Soil-dwelling organism Q-values through fipronil turf uses – 50% incorporation

Application rate (g ac/ha)	30	60	75
Q – earthworms	<<0.001	<<0.001	<<0.001
Q – non target terrestrial arthropods	0.25	0.75	0.62
Q – soil microorganisms	0.01	0.03	0.04

Table V4.26: Soil-dwelling organism Q-values through fipronil turf uses – 75% incorporation

Application rate (g ac/ha)	30	60	75
Q – earthworms	<<0.001	<<0.001	<<0.001
Q – non target terrestrial arthropods	0.37	0.75	0.92
Q – soil microorganisms	0.02	0.04	0.06

Table V4.27: Soil-dwelling organism Q-values through fipronil turf uses – 95% incorporation

Application rate (g ac/ha)	30	60	75
Q – earthworms	<<0.001	<<0.001	<<0.001
Q – non target terrestrial arthropods	0.47	0.95	1.17
Q – soil microorganisms	0.03	0.06	0.07

Based on acceptable levels of concern (Q values of 1 or less for earthworms and non-target terrestrial arthropods, EPHC 2009), the risk to earthworms and soil microorganisms is acceptable from granular use patterns. The only risk exceeding the acceptable risk quotient for other soil-dwelling invertebrates was at the highest application rate assuming 95% soil incorporation. At this rate, the risk was marginal (Q = 1.17).

This risk is readily mitigatable considering that turf application areas are likely to be small with large areas of untreated areas surrounding them. Therefore, no refined risk assessment will be undertaken for terrestrial invertebrates and soil microorganisms, and turf use patterns are considered acceptable for these organisms.

2.3.5. Group 7 products

It is clear from the LR50 value used for assessment of risk to terrestrial invertebrates exposed through spray (LR50 = 0.106 g ac/ha) that a high risk to insects exposed to the spray in the treated area exists. However, there is currently no model to assess potential spray from application equipment used to apply the termiticides, so risk outside the treated area resulting from spray drift can not be quantified.

Where applications are incorporated into the soil through trenching/rodding, the resultant soil concentration is in the order of 40 mg/kg soil. This will result in an acceptable risk to earthworms (Q = 0.04). However, risk to other soil-dwelling organisms in the treated area will be much higher (Q = 1000 based on NOEC = 0.04 mg/kg). Further, a risk to soil microorganisms can not be ruled out (Q <60).

Despite this, DEWHA previously concluded that, while the rate is very high, application will be directly to soil 15–30 cm away from existing structures where few, if any above ground terrestrial invertebrates are likely to occur. Therefore the hazard should be low. Since then, information has become available, and is reported in Volume 2, that showed fipronil was not mobile in soil when applied as either a surface treatment or a trenching treatment. Based on this, the original conclusions for non-target terrestrial arthropods and soil-dwelling invertebrates remains valid as there will be substantial areas of untreated soil remaining that will not be exposed to fipronil through sub-soil movement.

3. Conclusions from screening level risk assessment

The following conclusions relate only to parent fipronil, and have only considered a single application. Degradation of fipronil to its main metabolites does not represent a net gain to the environment as these metabolites are of similar toxicity as the parent compound. However, they are formed at <100% of the level of the parent compound, so for this screening level assessment, where an acceptable risk to fipronil is determined at the screening level, this is also considered to be acceptable to main metabolites. Consideration of degradation rates and metabolite toxicity is given for those uses/environmental compartments requiring a more refined risk assessment (Volume 5).

Table V4.28: Matrix of results of screening level risk assessment. Outcomes are shown as 'Y' for risk being acceptable, and 'N' for not-acceptable thereby requiring a refined risk assessment.

	Product group number								
	1	2	3	4	5	6	7	8	9
Aquatic organisms									
Fish – acute	N	N	Y	Y	Y	Y	N	Y	Y
Fish – chronic	N	N	Y	Y	N	Y	N	Y	Y
Aq. invertebrates acute	N	N	N	N	N	N	N	Y	Y
Aq. invertebrates chronic	N	N	N	N	N	N	N	Y	Y
Algae / aquatic plants	N	N	Y	Y	Y	Y	N	Y	Y
Sediment organisms (acute)	N	N	N	N	N	N	N	Y	Y
Birds, mammals and reptiles									
Birds, acute/dietary	N	N	Y	Y	Y	Y	Y	Y	Y
Mammals, acute	N	N	Y	Y	Y	Y	Y	Y	Y
Reptiles, acute	N	N	Y	Y	Y	Y	Y	Y	Y
Birds, chronic / reproduction	N	N	Y	Y	Y	Y	Y	Y	Y
Other non-target terrestrial organisms									
Bees	N	N	N	N	N	Y	Y	Y	Y
Non-target arthropods, exposure through spray	N	N	N	N	Y	Y	Y	Y	Y
Soil-dwelling arthropods, exposure through soil	N	N	Y	Y	Y	Y	Y	Y	Y
Earthworms	Y	Y	Y	Y	Y	Y	Y	Y	Y
Soil microorganisms	Y	Y	Y	Y	Y	Y	Y	Y	Y
Non-target terrestrial plants	No plant toxicity data available								

The screening level risk assessment, undertaken based on new data available since initial fipronil assessments in Australia, show that for the broadacre spray uses (groups 1 and 2), a refined risk assessment is needed for all organisms except soil microorganisms and earthworms. For products only registered for plague locust control (groups 3 and 4), the refined risk assessment will focus on aquatic invertebrates and sediment organisms (aquatic organisms), and bees and non-target arthropods exposed through spray (terrestrial organisms).

For all other groups, the risk to the terrestrial compartment was deemed acceptable. However, for seed treatment uses (group 5), turf uses (group 6) and termiticide uses (group 7) some further refinement of aquatic risk is required.

Based on the screening level risk assessment, uses from group 8 (fruit fly baits, product numbers 58478 and 60664) and group 9 (termiticide dust, product number 60654) remain acceptable with no further refinement of the risk assessment required.

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