



Appendix A

Terrestrial vertebrates

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INTRODUCTION

The procedures of risk characterisation are described according to the present state of knowledge. In this tiered assessment framework, potential risk for birds and mammals is identified on the basis of responses of individual organisms observed in controlled laboratory experiments, noting that the abundance and persistence of populations of organisms are potentially more relevant as endpoints for assessment than are responses of individual organisms. The proposed approach is justified on the ground that too little is known about the responses of populations to chemical exposure to support regulatory decisions on that basis; however, population modelling can be considered in higher tier assessments when sufficient information is available. Risk assessors have to consider, at least qualitatively, that if only a small fraction of a population is exposed (spatial scale) risks associated with the use of the pesticide product may be small even if some individuals would be affected. That does not preclude, that appreciable mortality without population level consequences may be judged unacceptable.

The standard risk assessment is based on the field scale and not landscape scale, ie the risk to non-target birds and mammals frequenting the treated field is assessed. No consideration is made of the risk from applications of the same pesticide to neighbouring fields. If concern is raised (ie $RQ > 1.0$) then the risk can be refined appropriately. When refining the risk it may be appropriate to consider such issues as suitability of the standard scenarios, scale of use and potential impact on populations. However, no deviations from worst case assumption should be made unless they are justified.

TOXICITY FIGURES

Acute:

- birds: LD₅₀ from acute oral test
- mammals: LD₅₀ from acute oral test.

Chronic:

- birds: NOEL from avian reproduction study.

Mammals:

- NOEL based on most sensitive endpoint of relevance for survival rate, reproduction rate
- development of individuals, for example results from multi-generation studies or teratology
- studies on mammals.

In each category the toxicity of the most sensitive test species is used. As a refinement, if more than one species has been tested in acute studies, a geometric mean of LD₅₀ values can be used.

With regard to chronic exposure in mammals, the assessment is conducted with a dose level that represents the no observed adverse effect level from a toxicological point of view. If the resulting RQ exceeds 1.0 then the ecological relevance of endpoints should be re-evaluated.

RISK ASSESSMENT

The major potential routes of exposure of terrestrial vertebrates are considered to be feeding on food items (eg vegetation and invertebrates) directly contaminated from spray application of the product. The acute and reproductive risks for terrestrial vertebrates following dietary exposure to contaminated food items are assessed using a tiered approach, which is in line with current EFSA (2009) guidance. The Australian assessment, however, first calculates a regulatory acceptable dose (RAD) for acute and chronic exposure scenarios as indicated in Table A1. A risk quotient is then calculated that compares the daily dietary dose for a 'worst case scenario' with the RAD.

For multiple applications, a default DT50 of 10 days is assumed for dissipation on food items. Foliar or insect dissipation data can be used to refine the assessment if it is shown that the dissipation of the active constituent is faster than assumed.

If it is necessary to refine the assessment, a Tier 1 assessment according to EFSA (2009) guidance is conducted which considers more specific exposure scenarios for generic focal mammal species relevant to the crop and timing of application (Table A3).

To further refine the assessment, a Tier 2 assessment considers that not all of the animal's daily diet is obtained in habitat treated with the pesticide (PT = fraction of diet obtained within the treatment area) or that not all of the animal's dietary items are available within the treatment area (PD = fraction of a particular food type in the diet). As a worst-case assumption at the screening and Tier 1 levels of assessment, animals are assumed to find all of their food (PT = 1) and dietary items (PD = 1) within the treatment area. The Tier 2 assessment considers more realistic estimates of PT or PD. Available sources of PT or PD data include:

- Aargard (2014) provides guidance on risk assessments for birds and mammals, based on the European Northern zone focal species relevant for the crop type and its growth stage. Biological background information on crop stage specific relevant focal species and available refinement options are presented
- Buxton et al. (1998) provides information on birds that occur in the agricultural environment in the UK and in particular their diet and breeding period. This publication can be used to help refine PD as outlined in EC (2002)
- Crocker et al. (1998a) provides information on the behaviour of birds in UK orchards. In particular, it provides useful information on the time that birds spend in orchards and hence can be used to refine PT as outlined in EC (2002)
- Finch et al. (2006) demonstrates how the proportion of diet obtained in treated areas by birds can be estimated from the recorded radio tracked 'active time' data and discussed the most appropriate percentile value for regulatory use in the current deterministic non-target bird risk assessment for pesticides
- Gurney et al. (1998) provides information on mammals that occur in the UK agricultural environment and in particular on their diet. This publication can be used to help refine PD as outlined in EC (2002)
- Prosser (2010) lists all the PT data from UK FERA's previous projects in a single document. Modelled PT distributions have been fitted to these data to give more accurately calculated 90th, 95th or other percentile points from the distributions.

For higher levels of assessment, it may be necessary to identify focal species for the specific crop(s) of concern. There are no Australian-specific focal species identified to date; however, there are some European publications

available that can be used to identify surrogate focal species for the same crops. Crocker and Irving (1999) highlights the type of work required to determine appropriate focal species, it also proposes several focal species for certain crops. Crocker et al. (1998b) summarises the influence of pesticide use, other aspects of husbandry and environmental factors on bird populations in orchards. Pascual et al. (1998) presents information on the occurrence of birds and mammals on arable fields in the UK.

For other refinement options:

- Crocker et al. (2002) can be used to determine for appropriate food intake rates (FIRs)
- Hart (2002) evaluated the feasibility of carrying probabilistic risk assessment. The report summarises several case studies and concludes that probabilistic risk assessment can be accommodated and could provide a significantly better basis for decision-making, if they are used appropriately.

Any additional refinements are likely to need additional data, either specific data on the product to be assessed or generic data. Some information may be available already in the dossier or can be produced by literature searches, other data have to be generated by new studies. As it is desirable to minimise animal testing other options for refinement should be explored first, where possible. In any case, the assumptions and input data in the refinement steps should be fully justified. It should be noted that refinement reduces the uncertainty and produces a more precise characterisation of the risk, but additional data do not necessarily result in a risk level that is lower than previously expected.

Home garden use

Hart (1999) provides information on the occurrence and subsequent use of non-target organisms in the home garden and should be consulted when the risk from a home garden is assessed as it highlights key species as well as issues associated with residues.

Seed treatments and solid formulations

Granular products

If granules are based on an organic carrier having a nutritional value then they may be taken by birds or mammals as food. In such cases, exposure could be assessed in a similar way as for baits or treated seeds. Granules with an inorganic base could be ingested either incidentally as birds and mammals inevitably incorporate a certain amount of soil when gathering food or intentionally when birds search for grit. The Tier 1 assessment followed the EFSA (2009) methodology considers the following scenarios:

- birds ingesting granules with/as grit (Table A4)
- mammals and birds ingesting granules when eating soil-contaminated food (Table A5)
- birds ingesting granules when seeking seeds as food (Table A6).

Seed treatments

The Tier 1 assessment according to EFSA (2009) assumes that granivorous mammals and birds feed entirely on readily available, freshly treated seeds (100 per cent of diet) assuming no incorporation into the soil (Table A6). Herbivorous and insectivorous mammals and birds are not considered to be attracted to fields immediately after treated seed has been drilled.

In general, granivorous mammals and birds prefer a certain type of seed for their diet. Not all birds are attracted to all sizes and shapes of seeds. Therefore, in a Tier 1 assessment, small granivorous birds that feed on small seeds, and larger medium-sized birds that feed on large seeds (such as maize, sugar beets and beans) are considered separately. A small omnivorous mammal is the indicator species for mammals, regardless of the seed size.

Slug pellets

Slug pellets are based on organic material and thus have a nutritional value for mammals and birds. It is known that small rodents like wood mice as well as granivorous birds ingest slug pellets if available (birds may take them as feed or as grit). As a starting point it could be assumed that animals feed exclusively on pellets. Suitable indicator species are the granivorous bird and the granivorous mammal from the standard scenarios. If a risk is indicated then palatability studies would be the most logical way to proceed because experience has shown that the attractivity of the pellets usually is limited. The pellets are coloured, and that feature among others may deter birds to a certain degree (EC 2002). Palatability studies should be conducted with the formulated product.

Other refinement options

Fryday et al. (1999) and (2001) provide useful information on the design of avoidance studies. These two reports should be consulted if an applicant is considering carrying out an avoidance study, or is assessing the risk to birds or mammals from a solid formulation.

In the case of seed eating birds and mammals, dehusking may reduce exposure. Regardless, whether seed treatment is the intended use of the product or weed seeds are contaminated during spraying, the substance will be mainly on the husk and therefore dehusking can remove the majority of the residue. This reduction can be as high as 85 per cent (EC 2002). Small birds are more likely to dehusk seeds than large birds, but it depends on the kind of seed, and even when dehusking occurs, only a proportion of seeds are dehusked. Prosser (1999) provides useful information on what seed is consumed by what bird.

Rodenticides

Rodenticides are inevitably toxic to mammals and birds, thus the risk assessment usually is a challenging task (EC 2002). Most rodenticides are anticoagulants that are far more toxic if consumed repeatedly over several days compared to a single dosing, which makes a short-term assessment more relevant than the acute assessment. Especially for mammals it may be necessary to take into account other toxicity figures than in the standard assessment, eg a five-day LD₅₀ which often is carried out for such substances.

Primary poisoning

Rodenticidal baits consist of cereals, grease or wax; therefore direct exposure is relevant mainly for rodents and seed eating birds. As rodenticides inevitably are toxic to non-target species, an exposure assessment that is based on exclusive feeding on the bait will always come to the conclusion of potential risk. Two refinement steps are obvious:

- consider accessibility of baits. Accessibility might be reduced by requiring appropriate use instructions to be put on the label:
 - baits placed in rooms or other enclosed spaces usually are inaccessible
 - baits placed in bait stations or are covered in some other way are fairly inaccessible to non-target species; occasionally small birds might have access to the bait if the quality of the cover is poor
 - baits placed sub-surface (burrow-baiting) are inaccessible to almost all non-target animals. The burrows of common voles or water voles are usually not used by other rodents
 - baits spread on surface are accessible to many non-target species depending on factors such as kind and height of vegetation.
- consider attractivity: Rodenticidal baits are designed to be attractive for rodents, so avoidance should not be expected. Often a bitter agent is added which repels children and carnivores but is unable to deter non-target rodents and birds. Nevertheless, the bait could be unattractive to birds to a certain degree due to colour, consistency and other factors, but that has to be tested before avoidance can be considered in the exposure estimate. Such tests could be conducted with a dummy formulation (which contains no active substance but is equal in all other features).

Secondary poisoning

Indirect exposure (secondary poisoning) can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas. For other situations a risk assessment for avian and mammalian predators and scavengers is necessary. In order to estimate the exposure quantitatively, a model calculation could be conducted based on a nominal concentration of the active substance in/on bait, bait uptake rate of target rodent, and estimated time to death of target rodent. However, such an estimate usually is unrealistically high as no elimination is assumed. Fortunately, in nearly all cases measured residues in rodents are available from different sources (special laboratory studies, secondary poisoning studies, monitoring of rodent control operations). For the purpose of exposure assessment, whole body residues are relevant (not liver residues). If a risk is indicated, the following options for refinement are possible:

- evaluate secondary poisoning studies that are already available for current rodenticides (Joermann 1998, EPPO 1995)
- improve estimate of proportion of target rodent in the diet of predators; suitable information might already be available from literature on feeding ecology; otherwise data could be generated using a marker in the bait
- field studies, monitoring.

Exposure scenarios

In addition to primary and secondary poisoning, EUBEES (2003a) has developed environmental exposure scenarios for the following situations:

- sewer systems
- in and around buildings
- open areas
- waste dumps.

Avicides

Non-target vertebrates are exposed to avicides primarily through consumption of treated food and secondarily from consumption of poisoned birds. EUBEES (2003b) has developed exposure scenarios with respect to uptake by non-target vertebrates.

RISK ASSESSMENT TABLES

Table A 1: Regulatory acceptable doses for terrestrial vertebrates

Taxonomic group	Exposure	Endpoint	Assessment factor	RAD
Birds	Acute	LD ₅₀ XX mg ac/kg bw/d	10	XX mg ac/kg bw/d
	Chronic	NOEL XX mg ac/kg bw/d	1	XX mg ac/kg bw/d
Mammals	Acute	LD ₅₀ XX mg ac/kg bw/d	10	XX mg ac/kg bw/d
	Chronic	NOEL XX mg ac/kg bw/d	1	XX mg ac/kg bw/d

Assessment factor.as per EPHC (2009)

RAD = regulatory acceptable dose = endpoint/assessment factor

Table A 2: EFSA (2009) shortcut values for screening level assessment of terrestrial vertebrates

Taxonomic group	Crop group	Indicator species	Shortcut value	
			Acute	Chronic
Bird	Bare soils and hops	Small granivorous bird	25.3	11.4
	Grassland	Large herbivorous bird	30.5	16.2
	Bush and cane fruit	Small frugivorous bird	52.2	23
	Orchards and ornamentals/nursery	Small insectivorous bird	46.8	18.2
	Vineyards	Small omnivorous bird	95.3	38.9
	Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, and sunflower	Small omnivorous bird	158.8	64.8
	Cotton	Small omnivorous bird	160.3	65.4
Mammal	Bare soil	Small granivorous mammal	14.4	6.6
	Bush and cane fruit	Small herbivorous mammal	81.9	43.3
	Bulbs and onion like crops, cereals, oilseed rape, potatoes, root and stem vegetables, strawberries, sugar beet, and sunflower	Small herbivorous mammal	118.4	48.3

Taxonomic group	Crop group	Indicator species	Shortcut value	
			Acute	Chronic
	Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses, and vineyard	Small herbivorous mammal	136.4	72.3

Table A 3: Screening level assessment of risks to terrestrial vertebrates

Group	Indicator species	Exposure	Shortcut value	Application rate (kg ac/ha)	DDD (mg ac/kg bw)	RAD (mg ac/kg bw)	RQ
Mammal		Acute					
		Chronic					
Bird		Acute					
		Chronic					

Shortcut value from Table A2

Cumulative application rate is based on maximum single application rate, number of applications, interval between applications and default DT_{50} 10 days

Acute DDD = daily dietary dose (mg/kg bw/d) = shortcut value * rate (kg ac/ha)

Chronic DDD = daily dietary dose (mg/kg bw/d) = shortcut value * rate (kg ac/ha) * time-weighted average factor 0.53

RAD = regulatory acceptable dose (from Table A1)

RQ = risk quotient = DDD/RAD, where acceptable $RQ \leq 1$

Table A 4: Screening level assessment of risks to terrestrial vertebrates

Group	Indicator species	Exposure	Shortcut value	Application rate (kg ac/ha)	DDD (mg ac/kg bw)	RAD (mg ac/kg bw)	RQ
Mammal		Acute					
		Chronic					
Bird		Acute					
		Chronic					

Shortcut value from Table A2

Table A 5 Screening level assessment of risks to terrestrial vertebrates ingesting granules when eating soil-contaminated food

Application rate (kg ac/ha)				
Taxonomic group	Mammal		Bird	
Exposure	Acute	Chronic	Acute	Chronic
Application rate (kg ac/ha)				
RAD (mg ac/kg bw/d)				
DGD (mg ac/kg bw/d)				
RQ				

Assessment method according to EFSA (2009)

RAD = regulatory acceptable dose (from Table A1)

Mammal acute DDS = daily dry soil dose (mg ac/kg bw/d) = 0.097 * application rate (kg ac/ha)

Bird acute DDS = daily dry soil dose (mg ac/kg bw/d) = 0.283 * application rate (kg ac/ha)

Mammal acute DDS = daily dry soil dose (mg ac/kg bw/d) = 0.005 * application rate (kg ac/ha) * time-weighted average factor 0.53

Bird chronic DDS = daily dry soil dose (mg ac/kg bw/d) = 0.025 * application rate (kg ac/ha) * time-weighted average factor 0.53

RQ = risk quotient = DGD/RAC where acceptable RQ ≤ 1

Table A 6: Screening level assessment of risks to terrestrial vertebrates ingesting granules when eating soil-contaminated food

NAR (mg acs/kg seed)						
Indicator species	Small omnivorous mammal		Small granivorous bird		Large granivorous bird ¹	
Type of seeds	Any		Small seeds (not maize, beans or peas)		Large seeds (maize, beans or peas)	
FIR/bw (kg seed/kg bw)	0.24		0.30		0.10	
Exposure	Acute	Chronic	Acute	Chronic	Acute	Chronic
RAD (mg acs/kg bw)						
RQ						

FIR/bw = food ingestion rate per body weight (from EFSA 2009)

NAR = nominal (loading) application rate of active constituent per kg seed

RAD = regulatory acceptable dose (from Table A1)

Acute RQ = risk quotient = NAR * (FIR/bw) / RAC, where acceptable RQ < 1

Chronic RQ = risk quotient = NAR * (FIR/bw) * time-weighted average factor 0.53 / RAC, where acceptable RQ ≤ 1

¹ This group also encompasses medium-sized birds for the purpose of refinement if necessary

RISK MITIGATION

Risk management options generally aim at a reduction of exposure. The possibilities of risk management very much depend on the type of product, the intended use, and specific conditions of the treatment area. Usually this is the final step in the assessment, but often it may be useful to envisage risk mitigation measures before all possibilities of refinement are exhausted. Whatever risk management option is chosen, the practicality should be assessed fully to ensure that it does not reduce the effectiveness and usefulness of the product.

Risk from spray application

If a risk to birds and mammals has been indicated from the use of a spray, then the risk may be reduced by decreasing the application rate and/or application frequency; however, this may significantly affect the efficacy of the product. Alternatively spot or row treatment may be appropriate depending upon the pest or disease being treated. Changing the method of application from spray to a more target approach, eg bait or paste/paint, may reduce the risk to birds and mammals; however, the success of this approach will depend upon the disease or pest being treated. If a reproductive risk to birds or mammals has been highlighted, then it may be appropriate to restrict the time of application when birds or mammals are not breeding, or to limit the number of applications and hence reduce exposure.

Risk from seed treatments

If a high risk from a seed treatment is predicted a label instruction should require the removal of spills immediately. Furthermore, it may be appropriate to consider that the seed treatment is only appropriate if the treated seed is drilled or incorporated below the soil surface at the time of sowing. If seed is incorporated, availability to birds and mammals will be reduced, and hence if an acute risk has been highlighted then this will be reduced as birds and mammals will take longer to find and consume treated seed. It has to be assessed, of course, whether consumption is reduced enough to conclude that the risk is acceptable.

Risk from granules

If a high risk from granules has been highlighted, again immediate removal of spills should be required and the feasibility of incorporating them at the time of application be considered in order to reduce the availability to birds. As for seed treatment, agronomic implications should be considered when assessing this as a risk management option.

Risk from rodenticides

The availability of baits to non-target birds and mammals can be reduced by prescribing burrow-baiting or the use of bait stations. When surface spreading is necessary then application should be on vegetation rather than on bare soil. As far as rodent control in and around buildings and similar premises is concerned, removal of dead and moribund rodents and removal of bait remains after completion of the control operation should be regarded as routine safety measures.

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