

Field efficacy of the Curiosity feral cat bait on three Australian islands

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Abstract Predation by feral cats (*Felis catus*) has led to declines in wildlife populations throughout Australia. Existing tools cannot achieve reductions in cat populations over large areas without presenting a hazard to wildlife. Para-aminopropiophenone (PAPP) formulations are being developed as new tools for the management of feral cat populations. The toxicant formulations are encapsulated within a degradable polymer. The combination of the toxicant formulation and encapsulation provides a robust pellet which is itself implanted inside a moist sausage bait. Pelletised toxicant delivery has been demonstrated to reduce exposure of non-target fauna to bait delivered toxicants. Field evaluations of the bait and pelletised toxicant delivery system have been undertaken at three island sites where the hazard to resident non-target species was minimal. In the first of these trials (April 2008), 6 of 8 radio-collared feral cats died following application of bait at 69 baits km⁻² over a 60 km² area within the French Island National Park (Victoria). In the second trial (April 2009), baits were aerially delivered at 50 baits km⁻² over a 250 km² area on Dirk Hartog Island (Western Australia). Sodium monofluoroacetate (1080) was substituted as the toxicant in this trial as engineering issues prevented production of the PAPP doses. Encapsulated pellets of the non-toxic marker Rhodamine B were implanted into 23% of baits and used as an indicator of cats that would have been expected to have died had PAPP pellets been available. Twelve of 15 radio-collared feral cats died following consumption of bait(s) and of these, nine were positive for Rhodamine. Feral cat activity, monitored over 4 x 10 km transects, indicated a twelve-fold decrease following baiting. For the third trial (August 2009), baits were suspended from purpose-built devices placed at 100 m intervals along the existing road network across an 85 km² area within Christmas Island National Park (Indian Ocean). Feral cat activity following baiting was reduced by 87% resulting from consumption of baits by a maximum of 78 feral cats. Further trials are planned for Australian mainland sites to collect efficacy data for purposes of obtaining agricultural chemical registration.

Keywords: *Felis catus*, para-aminopropiophenone, PAPP, efficacy, poison bait, encapsulation, GPS collar

INTRODUCTION

Populations of feral cats (*Felis catus*) first became established in Australia during the mid-1800s (Abbott 2002, 2008) and impact native fauna through direct predation, transmission of disease and competition for resources (Dickman 1996). Feral cats are defined as those animals that live and reproduce in the wild (e.g., forests, woodlands, grasslands, wetlands) and survive by hunting or scavenging with none of their needs satisfied intentionally by humans (Anonymous 1999).

Land managers have used shooting, trapping and/or exclusion fencing to manage feral cat populations in Australia but these techniques have limitations with respect to the area of effective control (Fisher *et al.* 2001). Less labour-intensive techniques, such as poison baiting, has mainly been limited to the arid zone of Western Australia, where surface-laid baits containing sodium monofluoroacetate (1080) is not considered to present a hazard to populations of non-target species due to their higher tolerances to the poison (McIlroy 1981; Algar and Burrows 2004). However, the native fauna of eastern Australia does not have similar tolerances to 1080 (McIlroy 1986; King 1990), which precludes broad-scale baiting for feral cats in these areas. The Australian Government listed the development of an effective toxin and bait for management of feral cat populations as a very high priority (Anonymous 1999; DEWHA 2008).

A collaborative project addresses this requirement through laboratory and field based studies to develop a bait that is humane, target-specific to feral cats and cost-effective. The Western Australian Department of Environment and Conservation (DEC) has previously developed a moist meat sausage bait (*Eradicat*) that consists of kangaroo, chicken fat and flavour enhancers (Algar and Burrows 2004). An automated dosing device injects 4.5 mg 1080 into each bait during production. Baits are air dried and then stored frozen until they are freighted in refrigerated condition to the field.

On the morning of use, baits are spread on elevated racks to thaw and 'sweat', a process in which volatile aromatic oils exude from the skin. A residual insecticide (Coopex, Bayer Crop Science, East Hawthorn, Australia) is lightly sprayed over baits which are then bagged and loaded into aircraft or ground-based vehicles for application. This bait has also been found to be attractive and palatable to feral cats at a south-east Australian temperate site (Johnston *et al.* 2007).

Para-aminopropiophenone (PAPP) is a toxicant with improved 'target specificity' based on the reported susceptibility of felids compared to other genera (Savarie *et al.* 1983; Fisher *et al.* 2008). This compound triggers the oxidation of haemoglobin to methaemoglobin, which is unable to transport oxygen (Bright and Marrs 1983). A series of pen trials were conducted to identify suitable PAPP formulations, inclusive of various 'solubilising' excipients and hard impervious coating matrices. An acid soluble polymer encapsulation structure houses the PAPP dose, preventing dispersion of the toxicant into the bait matrix. The hard impervious coating provides a robust toxicant pellet, termed the Hard Shell Delivery Vehicle (HSDV), which is reliably consumed by feral cats and conversely, rejected during feeding by many non-target species (Marks *et al.* 2006; Hetherington *et al.* 2007; Forster 2009; Johnston, *unpublished data*). When utilised with a HSDV, the *Eradicat* bait (without 1080) is known as the Curiosity bait.

In this paper, we describe field efficacy studies of the Curiosity bait, which were required to assist regulatory authorities with registration of the product as an agricultural chemical. We report on trials conducted on three Australian islands in different climatic zones: temperate (French Island – Victoria), semi-arid (Dirk Hartog Island – Western Australia) and tropical (Christmas Island – Indian Ocean). Island studies were the first to be undertaken to

enable investigation of the efficacy of the Curiosity bait in the absence of canids and domestic cats. There are also fewer extant species of non-target mammals at these sites compared to similar sites on the mainland.

MATERIALS AND METHODS

Site descriptions

French Island (38°21'S, 145°21'E), at 170 km², is located in Western Port approximately 70 kilometres south-east of Melbourne. The French Island National Park (FINP) covers 121 km² and includes salt marsh, heath, eucalypt woodland and pasture communities (Weir and Heislars 1998; Lacey 2008). Freehold areas on the island are grazed and include residences for permanent and absentee land-owners. Extant native mammal species include long-nosed potoroo (*Potorous tridactylus*), bush rat (*Rattus fuscipes*), swamp rat (*R. lutreolus*), water rat (*Hydromys chrysogaster*) and koala (*Phascolarctos cinereus*). Feral cats established within the National Park from strayed domestic animals and following historical deliberate releases (Lewis 1934). The baiting study was conducted in a 60 km² component of the FINP.

Dirk Hartog Island (25°50'S 113°0.5'E), at 620 km², is located in Shark Bay approximately 850 km north of Perth. The study was restricted to a 250 km² area in the north of the island, in spinifex grassland, low acacia or pittosporum shrub-land (Burbidge and George 1978). The western coast of Dirk Hartog Island (DHI) is rocky in contrast to the eastern coast which is largely sandy. No domestic animals are permitted on the island but there are herds of feral goats (*Capra hircus*) and sheep (*Ovis aries*). Feral cats became established on the island with pastoralists during the late 19th century (Burbidge 2001) and have been implicated in the local extinction of ten mammal species (Algar *et al.* 2011).

Christmas Island (10°29'S 105°38'E), at 135 km² is located approximately 2650 km north-west of Perth. This study was conducted along 50 km of existing tracks within the Christmas Island (CI) National Park and adjoining mine lease. Vegetation within the study area consisted of terrace soil evergreen rainforest amongst phosphate mining fields. Approximately 1300 people live in a community on the north-east coast. No ground-dwelling native mammal species remain on the island. However, native land crab species are abundant (Green 1997). A population of feral cats became established following the arrival of settlers in 1888 (Tidemann *et al.* 1994).

Baits, poisons and field application

The baits used in these studies resemble chipolata sausages and weigh approximately 15 g when dried. They are manufactured from 70% kangaroo meat mince, 20% chicken fat and 10% digest and flavour enhancers (Patent No. AU 781829) (Algar and Burrows 2004). Approximately 4100, 17000 and 7000 baits were used in the FINP, DHI and CI studies respectively. Baits used for the FINP study were prepared by the authors using domestic sausage manufacturing equipment from meat mince that had been buffered to pH ~8.0. The baits used in the DHI and CI studies were prepared at the DEC bait manufacturing facility and were not pH buffered. A HSDV implanted in one end of the meat baits contained a 78 mg PAPP formulation in the FINP and CI studies. The baits used on DHI were poisoned with 4.5 mg solution of 1080 and 23% of these were implanted with a HSDV containing 30 mg non-toxic Rhodamine B formulation.

Particular site characteristics and other logistical reasons necessitated differences in the method of bait application at each site as described below.

FINP: A Bell Jet Ranger helicopter flying at approximately 20 knots aerially distributed baits at a density of 50 baits km⁻² (i.e. 5 baits dropped every 10 seconds) on east-west transects spaced at 1000 metre intervals. Baits were also applied around the coast above the high tide line. A total of 3585 baits were dropped from the helicopter and 578 baits were laid along the track network at 100 m intervals from ground based vehicles. A 100 m buffer zone was not baited between the study area and private land. Overall baiting density was 69 baits km⁻². Baiting was undertaken on 29 April 2008.

DHI: Radio-collared cats were located on the morning of the baiting day from a single engine light aircraft equipped with VHF telemetry equipment. A flight plan was prepared for the baiting aircraft that consisted of 1 km² cells laid over a map of the study site. Baits containing the Rhodamine B HSDV were allocated to the cells where the collared cats had been located. The rest of the site was baited with baits that did not contain the HSDV. A twin engine aircraft flying at 130 knots at 500 feet ASL and guided by an AG-NAV navigation system, was used to drop 16,000 baits in accordance with the plan on 19 April 2009. A timing light indicated when the bombardier was to empty each bag of 50 baits into the drop tube to achieve the desired location and density of 50 baits km⁻². Follow-up baiting was undertaken on foot in the vicinity of collared cats that were still alive at >8 days and >13 days after aerial baiting (Johnston *et al.* 2010; Algar *et al.* 2011).

CI: Two baits, tied at the twist link, were suspended from each of 524 Bait Suspension Devices (BSD) (Algar and Brazell 2008) spaced at 100 m intervals along the roadside. A sand pad was formed underneath each device from crushed phosphate dust. Initially, non-toxic baits were provided at each bait suspension device across the site. Fresh baits, each containing a 78 mg PAPP HSDV, were provided following bait removal by a feral cat as evidenced by footprints on the sand pad (Johnston *et al.* 2010; Algar *et al.* 2010). Toxic baits were also supplied at bait suspension devices adjoining these active locations. All baits were replaced every four days to ensure they remained attractive but were not treated with Coopex. Baits were available for the period of 7 - 21 September 2009.

Monitoring

Feral cats were trapped during February 2008 (FINP) and March 2009 (DHI) within the study areas prior to the baiting programmes using padded leghold traps (Victor Softcatch, Woodstream, Pa.; USA). A blended mixture of cat faeces and urine 'Pongo' and a Feline Attracting Phonic (Westcare Industries, Nedlands, Western Australia) were provided at each trap set. Trapped cats were sedated with an intramuscular injection of an estimated 4 mg/kg Zoletil 100 (Virbac, Milperra; Australia). Cats were fitted with GPS datalogger / VHF transmitter collars that included a mortality mode feature and weighed 130 grams (Sirtrack, Havelock North; New Zealand). Radio-collared cats were released at the point of capture and subsequently monitored using an Australis VHF receiver (Titley Electronics, Ballina, Australia) fitted to a handheld yagi antenna or a uni-direction whip antenna fitted to the roof of a vehicle. Monitoring was initiated 14 days after baiting at FINP and two days after baiting on DHI. Transmitters were recovered if they were found to be in 'mortality mode'. Where possible, cause of death was established. PAPP toxicosis in the FINP study was confirmed by assessing presence of bait in the stomach and/or the colour of soft tissues in the mouth. A pale blue colour indicated a deoxygenated condition consistent with PAPP toxicosis. The gastro-intestinal tract was inspected for red staining in the DHI study indicating consumption of the Rhodamine B-HSDV.

Table 1 Morphometrics and fate of collared feral cats at French Island National Park. Baiting was undertaken on the 29th April 2008.

ID	Sex & body weight	Note
0400	Male 3.0 kg	Animal died 29 April. Multiple baits in stomach
1200	Male 3.4 kg	Animal not in baited area. Animal died 24 May following distribution of additional baits on 22 May. Bait in stomach.
1400	Male 3.6 kg	Survived. Animal initially outside baited area. Entered baited area on 1 May.
1600	Male 3.3 kg	Survived. Always within baited area.
1800	Male 3.8 kg	Died 1 March from unknown cause
2400	Female 2.2 kg	Died 11 April from unknown cause.
2600	Female 2.6 kg	Animal died 30 April. Multiple baits in stomach.
3000	Female 2.6 kg	Animal died 29 April. Multiple baits in stomach.
3600	Female 2.8 kg	Data stopped 28 April. Carcass recovered 16 May. Multiple baits in stomach.
3800	Male 3.4 kg	Animal died 29 April. Furred skeleton when recovered on 24 July. Probably died from bait consumption.

Activity monitor plots were constructed at 500 m intervals on the existing track network throughout the study areas using existing soil or suitable substrate transported to the site. Lures were provided at each monitor plot to increase visitation by feral cats, including the Felid Attracting Phonic, feline scent and/or food (pilchard and fried beef liver). These lures were different from those used in the trap sets and were removed when the plots were not being assessed. Cat visitation at the monitoring plots was recorded over five consecutive nights prior to and following baiting to generate a Plot Activity Index (PAI). This index is expressed as the mean number of sand pads visited by the target species per night. The PAI is formed by calculating an overall mean from the daily means (Engeman *et al.* 1998; Engeman 2005). The VARCOMP procedure within the SAS statistical software package produced the variance component estimates. The PAIs before and after baiting were compared using a z-test (Elzinga *et al.* 2001).

As bait station activity on CI could not be ascribed to individual feral cats, a value for the maximum and minimum number of cats poisoned was determined. The total number of toxic baits removed was considered to indicate the maximum number of individuals poisoned. The minimum number of individuals poisoned was calculated by ascribing bait removals from consecutive BSDs to the same animal, even if ten or more stations were involved. The actual number of feral cats poisoned during this programme would be between these two extremes.

RESULTS

French Island National Park

Twelve feral cats were trapped within the study area with collars fitted to six males (3.0 – 3.8 kg) and four females (2.2 – 2.8 kg). Eight of the ten collared cats were known to be alive when baits were distributed. Four cats died as a result of bait consumption as determined by inspection

Table 2 Plot Activity Index for feral cat activity at monitor plots (unbaited area n=30, baited area = 102) on French Island.

	Activity Index	Variation	Standard error
Control zone pre-bait	0.080	0.0005	0.023
Control zone post bait	0.280	0.001	0.036
Baited zone pre-bait	0.011	0.00002	0.005
Baited zone post bait	0.009	0.00001	0.004

of stomach contents (Table 1). The body of another had deteriorated sufficiently to preclude confirmation of PAPP toxicosis when it was recovered. However, the GPS data for this cat indicated that movement ceased on 29 April (i.e. the day that baits were applied), so it is probable that this cat had also consumed baits. Three collared cats were found alive during the post-baiting monitoring period. One cat was consistently found outside the baited area so 10 additional baits were laid in its vicinity on 22 May. This animal died on 24 May, with PAPP toxicosis confirmed as the cause of death. GPS data indicated that another of the surviving cats was initially outside the baited zone but should have encountered baits on 1 May while the other was always within the baited area. The assessment of feral cat activity on FI at monitor plots conducted prior to and following baiting proved, in this trial, to be inconclusive in the baited area (Table 2). However, an increase in activity at the monitor plots was observed in the unbaited area.

Dirk Hartog Island

Twenty-one feral cats were trapped within the study area and collars were fitted to 12 males (3.2 – 5.5 kg) and 4 females (3.5 – 3.7 kg). Fifteen collared cats were known to be alive when baits were aerially distributed. Twelve of these cats died after consuming at least one bait; of these, Rhodamine B stain was observed in the gastro-intestinal tracts of nine (Table 3). Three cats were shot as they had not consumed baits by the 1st May (i.e. 12 days after aerial baiting). Two dead uncollared feral cats were located

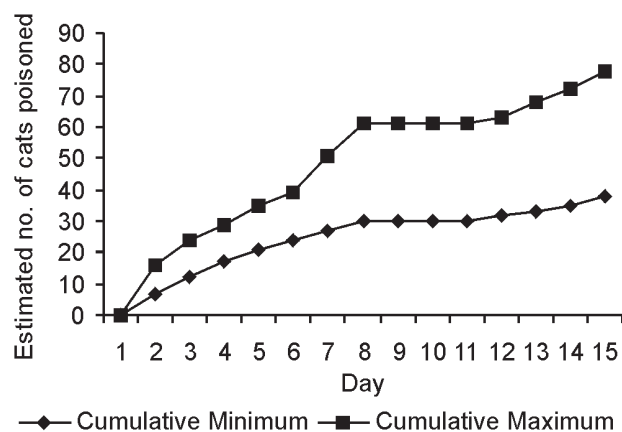

Fig. 1 Cumulative toxic bait removal by feral cats on Christmas Island.

Table 3 Morphometric details and fate of collared feral cats at Dirk Hartog Island. Aerial baiting was undertaken on the 19th April 2009.

Cat ID	Sex & weight	Date & Cause of Death	Comments
DH5	Male 5.1 kg	20 April – Bait	Rhodamine B dye observed
DH5_1	Male 4.2 kg	23 April - Bait	No Rhodamine B dye observed
DH12	Male 5.0 kg	22 April - Bait	Rhodamine B dye observed
DH17	Male 5.0 kg	29 April – Bait	Rhodamine B dye observed
DH27	Male 5.1 kg	2 May – Shotgun	
DH27_2	Male 4.5 kg	20 April – Bait	Rhodamine B dye observed
DH29	Male 4.7 kg	1 May – Shotgun	
B1	Male 3.8 kg	31 March - Unknown	Body recovered 19 April
B2	Female 3.5 kg	27/28 April - Bait	No Rhodamine B dye observed. Bait laid 27 April
B3	Female 3.7 kg	27/28 April – Bait	No Rhodamine B dye observed. Bait laid 27 April
MB2	Male 3.2 kg	20 April – Bait	Rhodamine B dye observed
MB3	Male 3.2 kg	20 April – Bait	Rhodamine B dye observed
MB5	Female 3.7 kg	20 April – Bait	Rhodamine B dye observed
MB6	Male 4.7 kg	20 April – Bait	Rhodamine B dye observed
MB7	Female 3.5 kg	20 April – Bait	Rhodamine B dye observed
MB8	Male 5.5 kg	4 May – Shotgun	

following baiting and both (c. 4 kg male, C. 3.5 kg female) showed Rhodamine B stains in their gastro-intestinal tracts. A comparison of PAIs before and after baiting (Table 4) indicated an 83% reduction in plot activity after the baits were applied ($z = 3.27$, $P < 0.001$).

Christmas Island

Cat visitation was recorded on 96 of the 524 BSDs (18%). Of these, 55 BSDs were visited on more than one night (57%), sometimes multiple times over the baiting period while 41 BSDs were visited only on the one night (43%). Two hundred and sixty-five (3.3%) of the 7860 bait nights accumulated in the study were toxic. A total of 183 baits were removed by feral cats over this period of which 78 (42%) were toxic. The total number of toxic baits removed, and by inference the maximum number of individual feral cats poisoned, was 78 (Fig. 1). The minimum number of individuals poisoned was 38 cats. Feral cats removed non-toxic baits from BSDs without making a return visit when toxic baits were available on 43 occasions.

A comparison of the PAIs before and after baiting (Table 4) indicated an 87% decline in feral cat activity after the baits were spread ($z = 3.17$, $P < 0.001$).

DISCUSSION

Curiosity baits achieved a considerable reduction (or dye-marking) in the feral cat populations and decreased measured cat activity at monitoring plots in all three sites tested. Activity monitoring plots and sandy tracks inspected at FINP indicated low feral cat activity within the study area prior to baiting when compared to the activity in the non-baited area. However, sufficient cats for a statistically

robust study were monitored with collars in the baiting area. Data from the GPS dataloggers suggest that baits were consumed by cats within two days of application. Two surviving cats should have encountered bait within three days of application, but no attempt was made to determine whether these cats had consumed bait and survived. It is not possible to determine whether cats consumed aerial or road delivered baits. However, the use of aerial baiting probably led to improved bait acceptance compared with previous studies at this site that only utilised road baiting (Johnston *et al.* 2007). The GPS dataloggers indicated that feral cats made greater use of the dense heathland vegetation than previous studies had indicated (McTier 2000).

Engineering failures prevented manufacture of sufficient HSDVs in time for the DHI trial. Modification of the trial design, which utilised the available stock of Rhodamine B HSDVs in *Eradicat* baits with 1080, provided an adequate alternative to assess the expected efficacy of PAPP. However, conclusions from the results in the DHI study were limited by: i) unavailability of PAPP and ii) only 23% of baits were implanted with Rhodamine B-HSDV's. Nonetheless, *post mortem* examinations after baiting indicated that 80% of the collared cats died following consumption of bait. Changes in feral cat activity on the activity monitor plots following baiting indicates that a significant decrease in activity was achieved. Our data suggest that 10 cats consumed aurally laid baits and 2 were probably poisoned by hand laid baits. Rhodamine B dye was observed in 75% of the cats that died from bait consumption. One collared cat died following consumption of an aurally-delivered bait but did not show any Rhodamine B stains. Unfortunately, as a result of the collar having ceased to collect data, it is not possible to determine whether: i) this cat had moved out of the zone where baits containing the Rhodamine B HSDV had been applied, or ii) it had encountered bait but rejected the HSDV during feeding.

The activity and abundance of land crabs as effective food scavengers on CI required modified baiting procedures (BSDs) to ensure adequate bait availability to feral cats. Previous studies of BSDs demonstrated that they effectively delivered baits to feral cats while minimising access to baits by non-target species (Algar and Brazell 2008). Local land management agencies also required that species removing baits be identified prior to use of a toxic

Table 4 Plot Activity Index (PAI) for feral cat activity at monitor plots on Dirk Hartog Island ($n=80$) and Christmas Island ($n=50$).

Site	Time	PAI	Variation	SE
DHI	Pre-baiting	0.078	0.00035	0.019
DHI	Post-baiting	0.013	0.00004	0.006
CI	Pre-baiting	0.060	0.00023	0.015
CI	Post-baiting	0.008	0.00003	0.005

bait which ensured that a minimum number of toxic baits were utilised. More cats may have been poisoned if toxic baits had been provided across the site from the outset, given the 43 instances when a BSD was not revisited. The actual number of feral cats poisoned following consumption of the Curiosity bait was between 38 and 78 individuals (Johnston *et al.* 2010; Algar *et al.* 2010). A more accurate figure cannot be determined given that the identification of individual cats was not possible using the sand pads and that it was likely that some cats visited multiple BSDs prior to the onset of symptoms associated with PAPP toxicosis. Nonetheless feral cat activity at the monitor plots was reduced by 87% during the study demonstrating effectiveness of the Curiosity bait. The very low rate of bait removals (1.3% of available baits) by non-target species could be further reduced using a residual insecticide and larger plates on the BSD (Johnston *et al.* 2010).

OVERALL OUTCOMES

Our data suggest that baits remain palatable and are consumed for at least 10 days after application but consumption was highest the day following bait application. Some feral cats probably consumed multiple baits during each of these trials given: i) the bait density used, and ii) that the first symptoms of PAPP toxicosis only become evident about an hour following bait consumption. If multiple bait consumption is confirmed, baiting density could be reduced or the distribution pattern altered to improve efficacy in terms of cost, ease of application, minimisation of hazard to non-target species or improving probability of bait encounter by all resident feral cats.

These studies demonstrated that feral cat populations can be effectively reduced utilising the Curiosity bait. The applicability of the HSDV for selective delivery of toxic compounds to feral cats has been demonstrated in these studies, but the need to identify and mitigate potential hazards to non-target species from the bait remains a high priority (Marks *et al.* 2006; Hetherington *et al.* 2007; Forster 2009; Johnston unpub. data). In particular, there are no published studies of the sensitivity of PAPP to Australian wildlife other than trials in New Zealand (Fisher *et al.* 2008) on common brushtail possums (*Trichosurus vulpecula*) and Australian magpie (*Gymnorhina tibicen*) (Eason *et al.* 2010). Limited testing has indicated that some other Australian species are highly susceptible (S. Humphreys pers. comm.). For example, species such as large goannas are expected to consume whole baits and are thus unlikely to reject the pellet. In such situations, the strategic timing of baiting operations to periods of reduced foraging activity may assist with: i) minimising bait consumption and ii) increasing bait acceptance by feral cats. Alternatively, different HSDV-toxicant formulations might be developed to which such species are less susceptible. The adoption of an encapsulated pellet prevents dispersion of the toxin throughout the bait medium, which reduces the amount of toxin provided per bait relative to a toxin delivered via an aqueous carrier. Combined with reduced baiting density and/or an altered distribution pattern, there is thus reduced potential for multiple bait encounter by non-target species which diminishes the risk of them ingesting a cumulative toxic dose.

Further trials of the Curiosity bait are planned for Australian mainland sites in the temperate, semi-arid and tropical zone to generate sufficient efficacy data for registration of the bait as an agricultural chemical. A necessary component of these trials will be monitoring and reporting on the impact of baiting operations on populations of non-target species. The use of this bait and toxicant

delivery technique may have international application for the management of feral cats or other carnivores. Additionally, the non-toxic Rhodamine B-HSDV can be utilised to provide land managers with a minimally invasive but effective risk assessment tool prior to the conduct of a toxic operation. Unit costs associated with the use of the Curiosity bait will be set by a commercial manufacturer licensed to produce the product.

ACKNOWLEDGEMENTS

This project was funded by the Department of Environment, Water, Heritage and the Arts. The interest and support provided by Julie Quinn, Belinda Parkes and others is recognised. We thank the land managers at each of the field sites for logistical assistance and interest in hosting these trials. Technical assistance was supplied by Mike Onus, Neil Hamilton, Sue Robinson, Stefanie Hilmer, Katrin Koch, Bruce Withnell, Peter Barker, Ben Fox and Michael Lindeman. Simon Humphrys (Invasive Animal Co-operative Research Centre) provided access to the data describing the susceptibility of selected Australian wildlife species to PAPP.

The APVMA approved field trial permits PER9905, 10634 and IOT0002. The Department of Sustainability and Environment approved research permit number 10004372 and AEC protocols 07/21 and 08/15. The Department of Environment and Conservation approved procedures under AEC protocols 2006/06 and 2008/29.

Comments by David Duncan, Lindy Lumsden and two anonymous referees improved this manuscript.

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